APPENDIX A

Committee Charter

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY CHARTER

FEDERAL ADVISORY COMMITTEE ON DETECTION AND

QUANTITATION APPROACHES AND USES IN CLEAN WATER ACT (CWA) PROGRAMS

---

1. Committee's Official Designation (Title):

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs

2. Authority:

This charter establishes the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in CWA Programs (FACDQ) in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 § 9 (c). FACDQ supports the Environmental Protection Agency (EPA) in monitoring and reporting chemical pollutants under the Clean Water Act (CWA).

The FACDQ is in the public interest and supports EPA in performing its duties and responsibilities.

3. Objectives and Scope of Activities:

EPA approves analytical methods (i.e., test procedures) used for monitoring and reporting chemical pollutants under the CWA. EPA's analytical methods specify detection limits to determine if a pollutant is present. Quantitation limits describe the concentration of a pollutant that can be measured with a known level of confidence. States, Tribes and EPA Regions that administer and enforce permit limits on direct discharges into water often use these values as reporting and compliance limits. Additionally, States and localities in administering and enforcing pretreatment programs for indirect discharges use these values. The major objectives of the FACDQ will be to provide advice and recommendations on approaches for the development of detection and quantitation procedures and uses of these procedures in CWA programs.

4. Description of Committee's Duties:

The duties of FACDQ are solely advisory in nature.

5. Official(s) to Whom the Committee Reports:

FACDQ will submit advice and recommendations and report to the EPA Administrator, through the Director, Office of Science and Technology, Office of Water.

6. Agency Responsible for Providing the Necessary Support:

EPA will be responsible for financial and administrative support. Within EPA, this support will be provided by the Office of Water.

7. Estimated Annual Operating Costs and Work Years:

The estimated annual operating cost of the FACDQ is $700K in FY05 and $350K in FY06 which includes 2.5 person-years of support in FY05 and 2.0 person-years of support in FY06.

8. Estimated Number and Frequency of Meetings:

FACDQ expects to meet approximately four (4) times a year. Meetings may occur approximately every three (3) months or as needed and approved by the Designated Federal Officer (DFO). EPA may pay travel and per diem expenses when determined necessary and appropriate. The DFO will be a full-time, or permanent part-time, employee of EPA. The DFO or a designee will be present at all meetings, and each meeting will be conducted in accordance with an agenda approved in advance by the DFO. The DFO is authorized to adjourn any meeting when he or she determines it is in the public interest to do so.

As required by FACA, FACDQ will hold open meetings unless the EPA Administrator determines that a meeting or a portion of a meeting may be closed to the public in accordance with subsection c of section 552b of Title 5, United States Code. Interested persons may attend meetings, appear before the Committee as time permits, and file comments with the FACDQ.

9. Duration and Termination:

FACDQ will be examined annually and will exist until the EPA Deputy Administrator determines the Committee is no longer needed. This charter will be in effect for two years from the date it is filed with Congress. After the initial two-year period, the charter may be renewed as authorized in accordance with Section 14 of FACA (5 U.S.C. App. 2 § 14).

APPENDIX B

History of Committee's Decisions

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs

Hilton Alexandria Old Town, Salons A & B

1767 King Street

Alexandria, VA

Tuesday – Wednesday, June 21-22, 2005

Decisions at Meeting #1

The committee: Committee members approved by consensus the revised ground rules for the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (20 Agree; 1 Absent).

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs

FDIC Seidman Center, Rooms 203 & 205

3501 Fairfax Drive, Arlington, VA

Thursday – Friday, September 29-30, 2005

Decisions at Meeting #2

The committee:

1. Approved, by consensus, the summary of the June 21-22 committee meeting.

2. Adopted, by consensus, working draft definitions of terms for use in the committee process with the understanding that the definitions would be refined as work progresses and decisions are made.

3. Developed and approved, by consensus, draft criteria to evaluate a final package of recommendations; the draft criteria will be finalized at a future committee meeting.

4. Created a Policy Work Group to: 1) identify and define uses of detection and quantitation; 2) identify the existing situation for each use category and data quality objectives for each type of use and user; and 3) pose policy issues that emerged in carrying out their assignments.

5. Tasked the Technical Work Group with: 1) proposing an approach or approaches for conducting a pilot test, including possible purposes and objectives of the pilot test; and 2) identifying existing data sources and their possible uses in a pilot test. The group was asked to expand the definitions of the characteristics in the evaluation matrix and to add to the glossary of terms, as necessary.

APPENDIX A: Committee Charter

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs

FDIC Seidman Center, Rooms 203 & 205

3501 Fairfax Drive, Arlington, VA

Thursday – Friday, December 8-9, 2005

Decisions at Meeting #3

The committee:

1. Approved, by consensus, the summary of Meeting #2, as drafted.

2. Approved changes to the description of the characteristics in the matrix, by consensus.

3. Approved, by consensus, revised goals for a final package of detection and quantitation recommendations.

4. Approved, by consensus, the draft pilot study purpose and objectives.

5. Approved, by consensus, to drop L_D for use in the single-lab pilot study.

6. Provided direction to the Technical Work Group in its further development of pilot studies requesting that the multi/inter-lab subgroup move forward with developing a pilot study design that incorporates a multi-lab study design and an inter-lab study design for the LCMRL procedure and present a draft design to the committee at the March 2006 meeting. The committee agreed to a stepwise pilot approach within the advisory process decision-making provisions. The term "multi-laboratory" will also be added to the glossary of terms.

7. Recommended, by consensus, further narrowed procedures for consideration in pilot testing by removing the Office of Solid Waste (OSW), ISO/IUPAC Quantitation Limit and Water Research Centre (WRC) procedures from pilot testing.

8. Agreed to the following responses to the Technical Work Group's questions related to a single-lab pilot study design:

    1. The committee agreed that the single-lab pilot study should include both descriptive and prescriptive approaches.

    2. The committee agreed that modification of procedures could be looked at, but that it should not be a high priority for the Technical Work Group. Most felt that changing procedures might happen after the pilot.

9. Approved, with amendments and by consensus, a framework for an interim report. The Policy Work Group was tasked with drafting the report that will be made available in time for committee members to check with their constituencies before the March 2006 committee meeting.

Final Report

APPENDIX A: Committee Charter

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (FACDQ)

FDIC Seidman Center, Rooms 203 & 205

3501 Fairfax Drive, Arlington, VA

Wednesday – Thursday, March 29-30, 2006

Decisions at Meeting #4

1. Meeting #3 Summary

The FACDQ approved by consensus the final summary of meeting #3 with amendments.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

2. What We Need Procedures to Do

A. Approved, by consensus, the following list of priority characteristics (not in priority order) for evaluating procedures[1]:

1. Is bias explicitly derived by the procedure?

2. Is precision explicitly derived by the procedure?

3. Does the procedure provide for selection of a Type I error tolerance limit (false positive)?

4. Does the procedure provide for selection of a Type II error tolerance limit (false negative)?

5. Does the procedure require that qualitative identification take place at the determined detection and quantitation limit?

6. Does the procedure adequately represent variability in lab performance?

7. Does the procedure describe how to modify a detection or quantitation limit for applicability to real world samples?

1 For a more thorough understanding of these characteristics, please refer to the following documents: "What Does the FACDQ Need a Procedure to Do?" (document #4 from the March 29-30, 2006 advisory committee meeting) and "Interpretation of Detection and Quantitation Procedure Evaluation Characteristics," from the December 8-9, 2005 FACDQ meeting.

8. Does the procedure evaluate the entire test method, including sample preparation and clean-up steps?

9. Does the procedure explicitly adjust or account for situations where method blanks always return a non-zero result/response (e.g., defects in calibration or consistent or chronic blank contamination of laboratory blanks)?

10. Does the procedure explicitly adjust or account for situations where method blanks are intermittently contaminated?

11. Is the procedure clearly written with enough detail so most users can understand and implement it?

12. Is the procedure cost-effective?

13. Is the procedure applicable to all users and test methods?

14. Does the procedure consider the differences between multi- and inter-lab approaches?

With respect to these characteristics, the committee also agreed to the following stipulations:

1. The characteristics depend on the uses the committee agrees to.
2. It is important to understand the specifics of the characteristics.
3. The characteristics for the procedures need on-going verification.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

B. Tasked a subgroup consisting of Richard Burrows, Tim Fitzpatrick, Michael Murray, John Phillips and Jim Pletl with incorporating comments from the five caucus groups into the narrative of what the committee needs procedures to do. The revised narrative will be presented to the committee in July.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

3. Uses of Detection and Quantitation

Tasked a subgroup consisting of Chris Hornback, Larry LaFleur, Tom Mugan, Michael Murray and Mary Smith to develop a straw proposal on the uses of detection and quantitation approaches in Clean Water Act programs, including permit limits, compliance enforcement, data reporting, and data reporting for reasonable potential determinations. In particular, the group will develop options to address the "delta" between L_C and

L_Q and other uses taking into consideration the committee's discussion of these topics.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed; 1 Absent

4. Measurement Quality Objectives

A. Agreed, for purposes of pilot testing, and by consensus, to set the false positive rate equal to or less than 1%.

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

B. Agreed, by consensus, that if or when data is reported below L_Q, then the data points that fall between L_C and L_Q would be reported, for example, as detected but not quantified (e.g., DNQ).

Vote: 19 Agree, 0 Not Opposed, 0 Opposed, 2 Absent

C. Agreed, by consensus, that determination of L_D is not a requirement for purposes of pilot testing, so long as data between L_C and L_Q is reported, for example, as detected but not quantified.

Vote: 19 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

D. Agreed, by consensus, to set, for purposes of pilot testing, the false negative rate equal to or less than 1% measured at L_C for the true value at L_Q or L_D.

Straw vote: 12 Agree, 8 Not Opposed, 0 Opposed, 1 Absent

E. Agreed, by consensus, that the goal for the pilot test of 20% relative standard deviation (RSD) is based on the mean recovery, understanding that there will be instances where this % RSD may show conflicts with accuracy (that is, set precision targets may inherently define accuracy targets). This may not be applied universally after the pilot study is complete. The study design team will consider higher precision targets (higher % RSD) if the goal cannot be met.

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

F. Agreed, by consensus, that, for the pilot, the study design team will ask participating laboratories to use accuracy based on mean accuracy and that the Technical Work Group study design team should make

decisions on specific goals for accuracy based on an evaluation of existing data. The study design team will ensure that the batch-by-batch data is available for the FACDQ to have analyzed.

Vote: 16 Agree, 3 Not Opposed, 0 Opposed, 2 Absent

5. Pilot Study Design

A. Agreed, by consensus, to task the Technical Work Group and a "Study Design Team" consisting of one person from each caucus on the Technical Work Group with scoping the details of the pilot study.

Vote: 19 Agree, 1 Not Opposed, 0 Opposed, 1 Absent

B. Agreed, by consensus, to proceed with pilot testing the following five analytical methods:

- 200.7 (metals),
- 300.0 (ions),
- 625 (SOCs),
- 608 (PCBs, pesticides)
- 335.3 (cyanide)

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (FACDQ)

FDIC Seidman Center, Rooms 203 & 205

3501 Fairfax Drive, Arlington, VA

Thursday – Friday, July 13-14, 2006

Decisions at Meeting #5

The committee:

1. Agreed to further refine the document describing characteristics the committee wants in a final procedure by:

    - Adding language in the introduction to read: "…the committee generally agreed that the list of characteristics should be built with the final recommendations in mind and that those characteristics should drive the pilot study to test whether procedures met those characteristics. Committee members also generally agreed that the pilot test was an opportunity to inform the committee's final recommendations and that some of the characteristics might be refined as a result of the pilot study data."

    - Revising characteristic 5b to read: "Requiring revision of L_Q or L_D if all spikes at L_Q or L_D are not detected."

    - Adding a new number 7 that would read: "Perform on-going verification of estimates. To be evaluated by:

        1. Continuously analyzing periodic blanks to assess the estimate of L_C;

        2. Continuously analyzing periodic low-level spike samples near L_Q to assess the estimate of L_Q; and

        3. Recalculating limits at a frequency that captures variability in performance relative to MQOs."

    - Removing the appendix.

Vote: Agree = 19; Not Opposed = 1; Opposed = 0; Absent = 1

2. Accepted the pilot study design, excluding Attachment B, and recommended moving forward with the pilot study.

Vote: Approve = 18; Not Opposed = 1; Opposed = 0; Absent = 2

3. Agreed to send the "Features" document back to the Technical Work Group to provide more detail about what the pilot study would not do.

4. Agreed to a revised title for proposal #6 in the straw uses proposal. The new title and proposal were as follows:

    - Uses for 303(d) Listing: Do not develop recommendations for how to use data for 303(d) listings for the following reasons:

        - 303(d) listing is a complex process that does not depend totally upon Part 136 analytical methods; it would require an effort to fully educate the committee on this process.

        - However, if an opportunity arises to link the 303(d) listing process to uses and approaches for detection and quantitation, and if the FACDQ becomes educated about the 303(d) listing process, then the FACDQ could revisit this issue prior to the final recommendations.

Vote: Approve = 20; Not Opposed = 0; Opposed = 0; Absent = 1

5. Agreed to postpone approving the draft summary of Meeting #4 until the next FACDQ meeting. In the meantime, another draft of the discussion surrounding the decisions on MQOs will be prepared using transcripts from the meeting. Both the transcription and redraft will be shared with a small group of representatives from the caucuses to ensure accuracy of the discussion for purposes of approving the summary at the December meeting. The committee also agreed to include a statement about revisiting the setting of numerical MQOs after completion of the pilot study.

6. Agreed to add another meeting to the existing schedule. The new meeting will be Wednesday, December 6 – Friday, December 8, 2006, at the FDIC Seidman Center in Arlington, VA. The committee also agreed to discuss extending the charter with Michael Shapiro and Ephraim King during their afternoon visit with the committee on day 2.

APPENDIX A: Committee Charter

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (FACDQ)

FDIC Seidman Center, Rooms 203 & 205

3501 Fairfax Drive, Arlington, VA

Wednesday – Friday, December 6-8, 2006

Decisions at Meeting #6

---

1. Groundrules

Environmental Community Caucus member Rob Moore resigned; as a result, the committee now consists of 20 members. The committee agreed to amend the groundrules to reduce the number required for a quorum by one, from 17 to 16. The language now reads as follows: "The committee will take no official action, such as offering advice or recommendations, with fewer than 16 participating Advisory Committee members."

Vote: 20 Agree, 0 Not Opposed, 0 Disagree

2. Meeting Summary #4

The committee agreed to approve the summary from Meeting #4 with the revisions suggested by a subgroup convened to recommend final language.

Vote: 20 Agree, 0 Not Opposed, 0 Disagree

3. Meeting Summary #5

The committee agreed to approve the summary from Meeting #5, with the following revisions:

- Move action box above section titled "Discussion of Data Analysis for the Pilot Study"
- Same section, third sentence, delete "…least helpful or…"
- Section titled "Discussion of Uses" under the state alternative proposal, the note for items 4 and 5 should read "…estimated value for data greater (~~less~~) than…"

Vote: 20 Agree, 0 Not Opposed, 0 Disagree

4. FACDQ Recommendations on Policy Issues (See full text on pages 13 – 16)

The committee agreed to the general concepts outlined in the revised Recommendations on Policy Issues document and tasked the Policy Work Group with further refinements of the document. The committee:

- Supports the intent of the policy recommendations, as revised;
- Recommends that the Policy Work Group refine the language in the recommendations per the FACDQ discussion in December, and also those items highlighted [in gray scale] in the document; and
- Recommends that the Policy Work Group bring back to the FACDQ their refinements for final decision-making.

Vote: 19 Agree, 1 Not Opposed, 0 Disagree

5. Final Report Work Group

The committee agreed to task the Final Report Work Group with beginning work on the final report. The committee asked the work group to begin assembling a draft of the final document, leaving placeholders where necessary, for the committee to discuss at a future meeting.

Vote: 18 Agree, 0 Not Opposed, 0 Disagree, 2 Absent

6. Matrix Effects

The FACDQ recommends the Policy Work Group develop some guidance on the topic for the FACDQ to consider at a future meeting.

Vote: 18 Agree, 2 Not Opposed, 0 Disagree

7. Technical Work Group Assignments

The committee agreed to assign the following tasks, in priority order, to the Technical Work Group:

- Complete the pilot results, report and recommendations for presentation to the committee at its next meeting.
- Develop recommendations around a procedure or procedures for the committee to consider at its next meeting.

- Develop recommendations and other details for initial and on-going verification (time permitting).
- Develop a list of existing methods and associated priorities for detection and quantitation limits (time permitting).

Vote: 20 Agree, 0 Not Opposed, 0 Disagree

8. Policy Work Group Assignments

The committee agreed to assign the following tasks, in priority order, to the Policy Work Group:

- Complete refinements to the revised policy issues document, particularly highlighted sections.
- Develop recommendations on data quality objectives for the committee to consider at its next meeting.
- Develop recommendations on implementation issues, using earlier one-pager (from Mary Smith) and ideas from FACDQ6 meeting.
- Develop guidance on matrix effects for the committee to consider at a future meeting.
- Develop recommendations and other details for initial and on-going verification.
- Develop a list of existing methods and associated priorities for detection and quantitation limits.

Vote: 20 Agree, 0 Not Opposed, 0 Disagree

9. Working Definitions

The committee agreed to table the discussion of its working definitions for a future meeting.

APPENDIX A: Committee Charter

FACDQ Recommendations on Policy Issues

The FACDQ worked diligently at its sixth meeting in December 2006 to reconcile and reach agreement on the policy recommendations below.

T

The FACDQ:

- supports the intent of the following policy recommendations, as revised;
- recommends that the Policy Work Group refine the language in the recommendations per the FACDQ discussion in December and also those items highlighted [in gray scale] below; and
- recommends that the Policy Work Group bring back to the FACDQ their refinements for final decision-making.

Vote: 19 Agree, 1 Not Opposed, 0 Disagree

he FACDQ voted on December 8, 2006 on the language that follows. EPA's votes reflect the views of the Office of Water for Clean Water Act Programs.

[Note: must clarify lab-specific vs. national/state DL/QL vs. permit QL throughout the document.]

APPENDIX A: Committee Charter

1. **Lab-Determined Detection Limits (DLs) and Quantitation Limits (QLs)**[1]

   Recommendation: The FACDQ recommends that EPA promulgate the descriptive single-laboratory procedure recommended by the FACDQ for individual laboratories to determine their actual detection and quantitation limits. The FACDQ further recommends that this descriptive procedure replace the one currently in 40 CFR Part 136 Appendix B.

2. **Method Promulgation**

   Recommendation: The FACDQ recommends that when the EPA promulgates future analytical methods in 40 CFR Part 136, detection limits (DLs) and quantitation limits (QLs) shall be included with the methods using the procedure recommended by the FACDQ. These limits will serve to define the minimum required performance of a laboratory, and may assist in comparing performance of one method to another (facilitating selection of a method most suitable for a given use), and may define important thresholds for use in evaluating compliance. (See the section titled "NPDES Permits and Compliance Uses.") The limits will be published in a table in a promulgated rule in 40 CFR Part 136.[2]

3. **Demonstration of Laboratory Proficiency of Detection and Quantitation Limits**

   Recommendation: The FACDQ recommends developing a process for initial and on-going verification of DLs and QLs by laboratories. This recommendation includes the following guidance:

- The FACDQ recommended procedure (e.g., what goes into 40 CFR Part 136 Appendix B) should include the on-going demonstration (either explicitly within the procedure or as an "attachment" if the FACDQ chooses to recommend a consensus procedure).

- Separate initial vs. on-going demonstrations.

- Strive for feasibility, practicality, representativeness and cost-effectiveness.

4. **Future Updates of Promulgated Analytical Method DLs and QLs**

   Recommendation: The FACDQ recommends that EPA periodically review current capabilities of promulgated analytical methods. The focus of this review should be on methods where there have been significant improvements in detection or quantitation limits or on methods that do not contain DLs or QLs. This review would be particularly important for cases where detection and quantitation limits are critical to the permit program (e.g., those required for very low WQBELs). EPA should focus on analytes for which current methods provide poor performance or do not meet program needs. Using best judgment and where resources are available, EPA shall update DL and QL limits on an on-going basis. EPA should also consider information submitted by states and/or other qualified third parties. EPA shall publish an annual Advanced Notice of Proposed Rulemaking (ANPR) announcing the DLs and QLs they propose to update.

---

1 The Policy Work Group agreed to use the terms DL for detection limit and QL for quantitation limit.

2 The Policy Work Group has agreed to incorporate a new table of promulgated detection and quantitation limits in a rule, but the Group has not had a full discussion of what would be included in the table.

5. **Recommendations for NPDES Permits and Compliance Uses for WQBELs below QL:**

Recommendation A:

The FACDQ recognizes that the existence of WQBELs at concentrations less than method QLs presents a number of NPDES-related issues. These include appropriate approaches for:

- Calculating monthly averages,
- Determining compliance with daily maximum limits and monthly average limits,
- Reporting data, and
- Appropriate compliance response in light of data uncertainty and the need for the protection of public health and the environment.

To deal with these various issues, the FACDQ recommends a balanced response as outlined below.

States that have been delegated the NPDES program from EPA have the authority under the Clean Water Act to adopt regulatory provisions that are different, but no less stringent than, those required under federal regulations. Such state-adopted provisions that would operate in lieu of the following recommendations could include a QL value lower than the nationally promulgated QL. In that case, the QL applicable under the state program would be used for determining compliance, reporting, and other applicable requirements.

i. The FACDQ recommends that a Part 136 DL and QL determined by the procedure recommended by the FACDQ be promulgated for each method/analyte combination which shall be the upper bound for lab performance. The default QL is the Part 136 promulgated value, unless states adopt an alternative but no less stringent approach. The permit must include the applicable QL. The NPDES permit must contain language that requires the use of a Part 136 method with a QL at or below the WQBEL. If no such method exists, the permit must provide that the appropriate method with the lowest QL be used. The facilities must require the lab to report lab-specific DLs and QLs as determined by the procedure recommended by the FACDQ and maintain such information for a period of at least five years. The FACDQ further recommends, for purposes of updating the Part 136 DLs and QLs, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

[Note: This needs work in terms of implementation, particularly with respect to Part 122 but not Part 123. For example, the FACDQ needs to consider what happens when the national QL changes during the life of the permit, and whether there were suggestions from the FACDQ to address that.]

ii. Set average and daily maximum permit limits at the WQBEL.

iii. While the FACDQ recognizes that values between a given laboratory's DL and QL have a higher level of uncertainty, the science suggests they are unlikely zero. However, assigning a non-zero value where an analyte is detected but not quantified (DNQ) would have significant compliance and enforcement implications. Therefore, assign zero for values less than the permit QL when determining average and daily maximum discharge levels.

iv. To determine NPDES permit compliance, compare average and daily maximum discharge levels, calculated in accordance with item (iii.) above, to the respective WQBEL.

v. A permittee must report to the permitting authority all information in the following manner:

When reporting daily maximum sample results:

1. For values less than the DL, report "ND" (not detected) on the DMR.
2. For values greater or equal to the DL and less than the QL, report "DNQ" (detected not quantified) on the DMR.
3. For values greater than or equal to the QL, report the actual values on the DMR.

When reporting averages:

4. Where all values used to calculate an average are less than DL, report "ND" on the DMR.
5. Where all values used to calculate an average are greater than or equal to DL but less than QL, report "DNQ" on the DMR.
6. When values used to calculate an average are a combination of ND and DNQ values, report "DNQ" on the DMR.
7. When any value used to calculate an average is greater than or equal to QL, report on the DMR the average as calculated in item (iii.) above.

Additional reporting requirements:

8. Report the lab-specific DL and QL and the individual numeric result for any value that is greater than or equal to the lab-specific DL and less than the permit QL in a supplemental report.

9. The permitting authority shall report the lab-specific DL and permit QL for each analyte to EPA in ICIS.

vi. Permits shall include language that triggers additional steps when a "significant number of" (to be determined in permitting process) DNQ values are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR reporting process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported according to the protocol in (v.).

Recommendation B: Current EPA guidance for implementing permit limits for WQBELs that challenge current analytical capabilities stipulates that the permit should specifically reference the most sensitive method approved in 40 CFR Part 136 and require its use to demonstrate compliance. The FACDQ recommends that EPA modify this reference to "the most appropriate method, taking into account sensitivity, selectivity and matrix effects" (i.e., "best method") and that EPA then incorporate this revised guidance into the regulation that it issues to implement the FACDQ recommendations.

5. **Matrix Effects**

Recommendation: The FACDQ recommends the Policy Work Group develop some guidance on the topic for the FACDQ to consider at a future meeting.

5. **Other Uses to Consider**

Recommendation: The FACDQ tabled the following list of additional uses:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization

- reasonable potential analysis

8. **Another Issue to Consider: Alternative Test Procedures**

   Recommendation: The FACDQ tabled the option of developing recommendations to EPA on updating the Alternative Test Procedures (ATP) program.

9. **Implementation of the FACDQ Recommendation**

   Recommendation: Initially, EPA would propose a new regulation that would essentially establish the recommendations of the FACDQ as regulations. This would include removing any current procedure (if that is the recommendation of the FACDQ), incorporating any recommended procedures, and making any other changes recommended by the FACDQ (e.g., new permitting regulations per our current discussion of uses).

   Once those regulations are in place, the procedures would be utilized in all future EPA method development/validation work and DLs and QLs would be promulgated with all new methods. As deemed appropriate by EPA, additional Federal Register notices and rulemaking would be used to update the detection and quantitation limits.

Final Report

APPENDIX A: Committee Charter

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (FACDQ)

Virginian Suites

1500 Arlington Blvd.

Arlington, VA 22209

S.S. Virginian Conference Center

Wednesday – Friday, June 6-8, 2007

Draft Summary of Meeting #7

Decisions at Meeting #7

1. Meeting Summary #6

The FACDQ agrees to approve the summary from Meeting #6, with the following revisions: Correction of name spellings for Tim Fitzpatrick and David Piller and removal of "(except California)" from locations within the document.

***Vote*: 18 Agree, 0 Not Opposed, 0 Disagree** *(6/6/07 AM)*

2. Pilot Study Results & Draft Pilot Study Report

The FACDQ agree to use the Pilot Study results and the May 24, 2007 Draft Pilot Study Report to inform decision-making on choosing a procedure(s).

***Vote*: 15 Agree, 1 Not Opposed, 2 Disagree** *(6/6/07 AM)*

NOT APPROVED

3. DQOs Decision

The FACDQ recommends that EPA Office of Water use the *EPA Guidance on Systematic Planning Using the Data Quality Objectives Process* in all Clean Water Act (CWA) programs.

Straw Vote: 17 Agree, 1 Not Opposed, 0 Disagree *(6/6/07 PM)*

***Vote*: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent** *(6/8/07 PM)*

4. Measurement Quality Objective (MQO) Decisions

A. False Positive Rate MQO

The FACDQ recommends that a ≤ 1% False Positive rate be used for Detection.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree *(6/6/07 PM)*

***Vote*: 17 Agree, 0 Not Opposes, 0 Disagree, 1 Absent** *(6/8/07 PM)*

B. Proposed Additional Language for MQOs – Future Methods

The FACDQ recommends that during the DQO process, EPA will give special attention to assuring the analytical method produces comparable results, at or near the QL_{nat}, on split samples, analyzed in different labs with the same method, and will specifically describe the steps taken in the proposed rule.

Straw Vote: 16 Agree, 1 Not Opposed, 1 Absent *(6/8/07 PM)*

***Vote*: 14 Agree, 3 Not Opposed, 0 Disagree, 1 Absent** *(6/8/07 PM)*

C. MQOs for Quantitation for Promulgated Methods

The FACDQ recommends that for promulgated methods in 40 CFR Part 136 without established MQOs, the initial MQO for Quantitation upon implementation of the new quantitation procedure is a specific False Negative rate (≤ 5%) to be implemented through a multiplier of the Detection Limit (determined by the FACDQ recommended Single Lab Procedure for Detection). The Precision and Accuracy MQOs for individual analytes/methods would be generated and promulgated, as the data to support those MQOs becomes available.

The FACDQ requests that the Technical Work Group establish or recommend a procedure to add MQOs to existing methods.

Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent *(6/7/07 PM)*

***Vote*: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent** *(6/8/07 PM)*

D. Limits for QL MQOs for Future Promulgation of New or Updated Methods

The FACDQ recommends the Technical Work Group develop recommendations for target MQO bounds for compliance and enforcement that define Quantitation. The TWG will bring these recommendations back to the FACDQ.

For example:

A. Precision ≤ 30% RSD

2. Accuracy (measured as recovery for single determination) = 20-180%

3. False Negative rate ≤ 10%

4. Ratio of Accuracy to Precision must be no less than 1.0

Example: 40% Recovery / 20% RSD = 2 O.K.,

Example: 20% Recovery / 30% RSD = .66 Not Acceptable

Straw Vote: 13 Agree, 5 Not Opposed, 0 Disagree *(6/8/07 PM)*

***Vote*: 12 Agree, 5 Not Opposed, 0 Disagree, 1 Absent** *(6/8/07 PM)*

E. MQO Bounds

The FACDQ recommends that EPA establish quantitative MQO bounds for relevant Data Quality Indicators (DQIs) that define Quantitation for intended CWA uses. These bounds would be offered for public comment by EPA.

Straw Vote: 13 Agree, 4 Not Opposed, 1 Disagree *(6/8/07 PM)*

***Vote*: 9 Agree, 7 Not Opposed, 1 Disagree, 1 Absent** *(6/8/07 PM)*

NOT APPROVED

F. MQOs for Future Promulgation of Methods

The FACDQ recommends, for future method promulgation, that target MQOs for DQIs, such as Precision, Accuracy, Method Specified Qualitative Identification, and False Negative error rates derived from the DQO process, be established for Quantitation Limits in Part 136. If the target MQOs cannot be met, EPA may promulgate with rationale.

Straw Vote: 9 Agree, 9 Not Opposed, 0 Disagree *(6/8/07 AM)*

The FACDQ recommends, for future method promulgation, that target MQOs for Precision and Accuracy derived from the DQO process be established for QLs in Part 136. In addition, DQIs such as method specified quality identification and False Negative error rate would be considered. If the target MQOs cannot be met, EPA may promulgate with rationale.

Straw Vote: 9 Agree, 5 Not Opposed, 4 Disagree *(6/8/07 AM)*

5. Multi/Inter Lab Approaches

A. The FACDQ asks the Technical Work Group to develop a recommended process for determining a QL_{nat}.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree *(6/8/07 AM)*

***Vote*: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent** *(6/8/07 PM)*

B. The FACDQ recommends that EPA promulgate how QL_{nat} is derived.

Straw Vote: 10 Agree, 6 Not Opposed, 2 Disagree *(6/8/07 AM)*

Straw Vote: 10 Agree, 7 Not Opposed, 1 Absent *(6/8/07 AM)*

***Vote*: 7 Agree, 10 Not Opposed, 0 Disagree, 1 Absent** *(6/8/07 PM)*

C. The FACDQ recommends that EPA develop a procedure for establishing a QL_{nat} using the framework identified by the FACDQ. The Technical Work Group will develop this framework for FACDQ consideration.

Straw Vote: 6 Agree, 10 Not Opposed, 1 Disagree, 1 Abstained *(6/8/07 AM)*

D. The FACDQ asks the Technical Work Group to develop a recommended procedure(s) for determining QL_{nat}.

Straw Vote: 16 Agree, 1 Not Opposed, 1 Disagree *(6/8/07 AM)*

E. The FACDQ recommends that EPA establish after public comment how QL_{nat} is derived.

Straw Vote: 9 Agree, 4 Not Opposed, 5 Disagree *(6/8/07 AM)*

F. The FACDQ recommends that EPA develop a Multi Lab Procedure for establishing a QL_{nat} using the framework identified by the FACDQ. The Technical Work Group will develop this framework for FACDQ consideration.

Straw Vote: 0 Agree, 1 Not Opposed, 13 Disagree, 4 Abstained *(6/8/07 AM)*

G. The FACDQ asks the Technical Work Group to develop a recommendation for a process that considers both Multi and/or Inter Lab Procedures in developing a QLnat.

Straw Vote: 13 Agree, 3 Not Opposed, 1 Disagree, 1 Absent *(6/8/07 AM)*

6. Recommendations on Procedures

A. The FACDQ recommends the Technical Work Group continue to develop the specifics for the following:

Single Laboratory Detection Limit Procedure

The ACIL Procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and LabQC Procedures, is recommended for a Single Laboratory Detection Limit Procedure.

***Vote*: 17 Agree, 1 Not Opposed, 0 Disagree** *(6/8/07 AM)*

B. The FACDQ recommends the Technical Work Group continue to develop the specifics for the following:

Single Laboratory Quantitation Limit Procedure

The ACIL Procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and Lab QC procedures, as well as decisions by the FACDQ at its June 2007 meeting.

***Vote*: 16 Agree, 2 Not Opposed, 0 Disagree** *(6/8/07 AM)*

7. Uses Decisions

A. DL_{nat}

The FACDQ recommends the Policy Work Group explore the deletion of DL_{nat}, the possible policy changes to the document, and their implications for bringing back to the FACDQ. The Policy Work Group will also explore other policy issues not completed at the June 2007 meeting.

Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree *(6/807 PM)*

***Vote*: 16 Agree, 1 Not Opposed, 0 Disagree, 1 Absent** *(6/8/07 PM)*

2. **Uses Document**

The FACDQ directs the FACDQ Work Groups to use the straw vote decisions as a starting point for writing the Uses portion of the Final Report and other activities subject to revisions based on a final vote to occur later.

***Vote*: 16 Agree, 0 Not Opposed, 0 Disagree, 2 Absent** *(6/8/07 PM)*

- ***A subscript "nat" is used to designate the nationally-promulgated DL or QL – DL_{nat} or QL_{nat}***
- ***A subscript "lab" is used to designate the laboratory-specific DL or QL – DL_{lab} or QL_{lab}***
- ***A subscript "per" is used to designate the permit-specified QL – QL_{per}***
- ***A subscript "st" is used to designate the state-optional DL or QL – DL_{st} or QL***

The FACDQ agreed to allow EPA come up with a new acronym for a situation where an analyte is detected below the QL_{per}. The acronym will replace "DNQ" and must fit into the conditions of the ICIS system. The facilitator used the acronym "DBQp" for purposes of completing this document. *(6/7/07 PM)*

4. **Lab-Determined Detection Limits (DL_{lab}s) and Quantitation Limits (QL_{lab}s)**

Recommendation: The FACDQ recommends that EPA promulgate the descriptive single-laboratory procedure(s) recommended by the FACDQ for individual laboratories to determine their Detection and Quantitation Limits. The procedure(s) should have the following two capabilities:

1. Demonstrate the lab's performance at a specified level.
2. Determine the lowest possible value achievable by the lab.

The FACDQ further recommends that the descriptive procedure(s) replace the one currently in 40 CFR Part

5. **Method Promulgation**

Recommendation: The FACDQ recommends that when the EPA promulgates future analytical methods in 40 CFR Part 136, Detection Limits (DL_{nat}s) and Quantitation Limits (QL_{nat}s) shall be included with the methods using the procedure(s) recommended by the FACDQ.

> The FACDQ agreed to remove all language referring to a published table of limits in a promulgated rule in 40 CFR Part 136 as well as the pre-existing footnote. *(6/7/07*

> The FACDQ also agreed to remove the following language though it was agreed that the Final Report Work Group would keep it under consideration when drafting an introductory paragraph: "These limits will serve to define the minimum required performance of a laboratory and may assist in comparing performance of one method to another (facilitating selection of a method most suitable for a given use), and may define important thresholds for use in evaluating compliance. (See the section titled "NPDES Permits and Compliance Uses, Recommendation 5.A & B")." *(6/7/07 AM)*

6. **Verification of Laboratory Proficiency of Detection and Quantitation Limits**

Recommendation: The FACDQ recommends developing a process for initial and on-going verification of DL_{lab}s and QL_{lab}s by laboratories. This recommendation includes the following guidance:

- The FACDQ recommended procedure (e.g., what goes into 40 CFR Part 136 Appendix B) should include on-going verification of DL_{lab} and QL_{lab} (either explicitly within the procedure or as an "attachment" if the FACDQ chooses to recommend a consensus procedure)
- Meeting MQOs for use
- Separate initial vs. on-going verifications
- Strive for feasibility, practicality, representativeness, and cost-effectiveness

> The FACDQ agreed to replace "demonstration" from this section with the word "verification" and to strike the pre-existing footnote and to add the bullet: "Meeting MQOs for use." *(6/7/07 AM)*

4. **Future Updates of Promulgated Analytical Method *DL_{nat}s* and *QL_{nat}s***

Recommendation: The FACDQ recommends that EPA periodically review current capabilities of promulgated analytical methods. The focus of this review should be on methods where there have been significant improvements in Detection or Quantitation Limits or on methods that do not contain DL_{nat}s or QL_{nat}s. This review would be particularly important for cases where Detection and

Quantitation Limits are critical to the permit program (e.g., those required for very low WQBELs). EPA should focus on analytes for which current methods provide poor performance or do not meet program needs. Using best judgment and where resources are available, EPA shall update DL_{nat} and QL_{nat} limits on an on-going basis. EPA should also consider information submitted by states and/or other qualified third parties. EPA shall publish a Federal Register Notice announcing the DL_{nat}s and QL_{nat}s it proposes to update. Provisions later in this document are for the purpose of providing EPA with robust data sets for updating and or creating DL_{nat}s and QL_{nat}s.

The FACDQ agreed to leave "4." as it is with the understanding that "shall" (…EPA shall update DL_{nat} and QL_{nat} limits on an on-going basis.) will remain. *(6/7/07 AM)*

4. **The FACDQ recognizes that the existence of WQBELs at concentrations less than quantitation limits presents a number of NPDES-related issues.** These include appropriate approaches for:

- Calculating monthly averages
- Determining compliance with daily maximum limits and monthly average limits
- Reporting data, and
- Appropriate compliance response in light of data uncertainty and the need for the protection of public health and the environment.

To deal with these various issues, the FACDQ recommends a balanced response as outlined below.

States that have been delegated the NPDES program from EPA have the authority under the Clean Water Act to adopt regulatory provisions that are different, but no less stringent than, those required under federal regulations. Such provisions, if authorized or not prohibited by state law, would operate in lieu of the following recommendations and could include a QL_{st} value lower than the nationally promulgated QL_{nat}. In that case, the QL_{st} applicable under the state program would be used for determining compliance, reporting, and other applicable requirements.

A. Recommendations for NPDES Permits and Compliance Uses where a QL_{nat} exists and for WQBELs at concentrations less than QL_{nat}. If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B:

APPENDIX A: Committee Charter

The FACDQ agreed to include the following language: "If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B."
Straw Poll: 14 Agree, 4 Not Opposed, 0 Disagree *(6/7/07 PM)*

1. The FACDQ recommends that a Part 136 DL_{nat} and QL_{nat} determined by the procedure recommended by the FACDQ be promulgated for each method/analyte combination which shall be the upper bound for lab performance. The regulator shall insert QL_{per}s in permit or in rule as appropriate. The default QL_{per} is the lowest Part 136 promulgated QL_{nat}. The regulator would then consider whether the method associated with this QL_{nat} is the most appropriate method considering sensitivity, selectivity, and/or matrix effects and adjust the QL_{per} accordingly.

The FACDQ agreed not to include the following language: "All the following does not apply if the QL_{nat} is not the most sensitive method QL_{nat}."
Straw Poll: 8 Agree, 8 Not Opposed, 2 Disagree

The FACDQ agreed to the following language: "…the method associated with this QL_{nat} is the most appropriate method considering sensitivity…"

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree *(6/7/07 PM)*

The FACDQ agreed to the following language: The regulator shall insert QL_{per}s in permit or in rule as appropriate.

Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree *(6/7/07 PM)*

2. The permit shall also contain a condition that the permittee's QL_{lab} shall be at or below the QL_{per}. The permit shall require permittees to report DL_{lab}s and QL_{lab}s as determined by the procedure recommended by the FACDQ and maintain such information for a period of at least five years.

The FACDQ agreed to remove the following language: "The QL_{per} shall be applicable for the term of the permit unless the regulator reopens and modifies the permit" as well as #3 with the two options regarding the life of the permit.

Straw Vote: 9 Agree, 9 Not Opposed, 0 Disagree *(6/7/07 PM)*

3. For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab}s and QL_{lab}s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab}s and DL_{lab}s.

The FACDQ agreed on the following language:
3) For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab}s and QL_{lab}s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab}s and DL_{lab}s.
Straw Vote: 10 Agree, 8 Not Opposed, 0 Disagree *(6/7/07 PM)*

4. The FACDQ further recommends, for purposes of updating Part 136 DL_{nat}s and QL_{nat}s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

The FACDQ agreed to return to the option of deleting the new **4)** if it is found to be duplicative in later sections of the document. *(6/7/07 PM)*

5. Implementation in NPDES Permits:

a) Set average and daily maximum permit limits at the WQBEL.

b) Assign zero for values less than the permit QL_{per} when determining average and daily maximum discharge levels.

The FACDQ agreed to rename the title of the new section 5 from:
"Recommendation for NPDES Permits and Compliance Uses for WQBELs when QL_{nat}s do exist" to "Implementation in NPDES Permits." *(6/7/07 PM)*

Rationale: While the FACDQ recognizes that values between a given laboratory's DL_{lab} and QL_{lab} have a higher level of uncertainty, the science suggests they are unlikely to be zero. However, assigning a non-zero value where an analyte is detected below the QL_{per} (DBQp) would have significant compliance and enforcement implications. Therefore, the committee recommends assigning a zero in these cases.

APPENDIX A: Committee Charter

The FACDQ agrees on the following language:

Note: The FACDQ agrees that this rationale concept is important and will be included in the Final Report.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree *(6/7/07 PM)*

1. To determine NPDES permit compliance, compare average and daily maximum discharge

The FACDQ agreed to change "above" to "below." *(6/7/07 PM)*

levels, calculated in accordance with item (d.ii.) below, to the respective WQBEL.

d) A permittee must report to the permitting authority all information in the following manner:

i. When reporting daily maximum sample results:

1. For values less than the DL_{lab}, report "ND" (not detected) on the DMR.

2. For values greater or equal to the DL_{lab} and less than the QL_{per}, report "DBQp" (detected below QL_{per}) on the DMR.

3. For values greater than or equal to the QL_{per}, report the actual values on the DMR.

i. When reporting averages:

1. Where all values used to calculate an average are less than DL_{lab}, report "ND" on the DMR.

2. Where all values used to calculate an average are greater than or equal to DL_{lab} but less than QL_{per}, report "DBQp" on the DMR.

3. When values used to calculate an average are a combination of ND and DBQp values, report "DBQp" on the DMR.

4. When any value used to calculate an average is greater than or equal to QL_{per}, report on the DMR the average as calculated in item (5.A.5.b) above.

The FACDQ agrees that DL_{lab} will remain in **i.** and **ii.** With the proviso that there will be consideration of this post the MQO discussion.
Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree *(6/7/07 PM)*

i. Additional reporting requirements:

1. The regulator shall require that the permittee report the DL_{lab} and QL_{lab} (for purposes of updating methods and to determine compliance with the conditions of the permit.) The permitting authority shall report the DL_{lab}, $QL_{lab,}$ and QL_{per} for each analyte to EPA in ICIS.

2. The regulator may require the individual numeric result for any value that is greater than or equal to the DL_{lab} and less than the QL_{per} be reported in a supplemental report.

The FACDQ agreed to the remove the second sentence in **iii.b**: "Potential uses would be to determine reasonable potential and for public knowledge."
Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent *(6/7/07 PM)*

3. The permittees shall maintain individual numeric results for a period of at least five years.

6. Permits shall include language that triggers additional steps when a "significant number of" (to be determined in the permitting process) DBQp values are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR reporting process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported according to the protocol in (5.A.5.d.iii).

B. Recommendations for NPDES Permits and Compliance Uses for WQBELs when no QL_{nat} exists:

1) In the absence of QL_{nat}, the permitting authority is free to establish it's method for determining compliance for analytes that have limits/water quality standards at a level lower than that which can be detected and/or quantified.

2) For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab}s and QL_{lab}s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab}s and DL_{lab}s.

The FACDQ agreed to **1)** and **2)**
Straw Vote: 17 Agree, 1 Not Opposed, 0 Disagree *(6/7/07 PM)*

3) The FACDQ further recommends, for purposes of developing Part 136 DL_{nat}s and QL_{nat}s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

Note: The FACDQ recommends that EPA reconsider the usefulness of this requirement after time.

The FACDQ agreed to the following language:
3) The FACDQ further recommends, for purposes of developing Part 136 DL_{nat}s and QL_{nat}s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).
Note: The FACDQ recommends that EPA reconsider the usefulness of this requirement after time.
Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree *(6/7/07 PM)*

7. Other Uses to Consider

Recommendation: The FACDQ tabled the discussion on recommendations regarding the use of Detection and Quantitation for other uses including but not limited to the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization
- reasonable potential analysis
- effluent guidelines development

- limit derivation
- development of water quality criteria

The FACDQ agreed to the language in the section "Other Uses to Consider."
Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent *(6/7/07 PM)*

8. Alternative Test Procedures

Recommendation: The FACDQ tabled the option of developing recommendations to EPA on updating the Alternative Test Procedures (ATP) program. The FACDQ recommends that the ATP program be updated to be consistent with recommendations in this document.

The FACDQ agreed to the language in the section "Alternative Test Procedures."
Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree *(6/7/07 PM)*

9. Great Lakes Initiative (GLI)

Recommendation: **The FACDQ recommends that FACDQ recommendations should not supersede the current GLI provisions. There is no significant conflict between the anticipated FACDQ recommendations and the GLI.**

The FACDQ agreed to the language in the section "GLI."
Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/8/07 PM)

8. Matrix Effects (Use 6.)

The FACDQ recommends that EPA consider how Matrix Effects impact Detection and Quantitation. The FACDQ requests that the Policy Work Group bring back a conceptual recommendation including details to be considered.

***Vote*: 17 Agree, 1 Not Opposed, 0 Disagree** *(6/8/07 PM)*

9. Implementation of the FACDQ Recommendation

The FACDQ recommends "9. Implementation of the FACDQ Recommendation" be removed from the Uses Document for consideration by a work group. However, the importance of these issues related to Uses should not be separated. A work group of the FACDQ is tasked with bringing recommendations on the implementation issues back to the FACDQ.

***Vote*: 18 Agree, 0 Not Opposed, 0 Disagree** *(6/8/07 PM)*

APPENDIX A: Committee Charter

APPENDIX A: Committee Charter

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (FACDQ)

Teleconference Meeting

1-866-299-3188

202-566-1045#

July 25, 2007, 1 PM to 4 PM EDT

Decisions at Meeting #8

1. Removal of DL_{nat}

The FACDQ approves the removal of DL_{nat} from the Revised Uses document.

***Vote*: 16 Agree, 2 Not Opposed, 1 Disagree**

NOT APPROVED

2. Uses Recommendation on MQOs for Future Promulgation of Methods

The FACDQ recommends, for future method promulgation, that target MQOs for Data Quality Indicators (DQIs), such as Precision, Accuracy, Method Specified Qualitative Identification, and False Negative error rates derived from the Data Quality Objectives (DQO) process, be established for Quantitation Limits in Part 136. If the target MQOs cannot be met, EPA may promulgate with rationale.

Straw Vote: 9 Agree, 9 Not Opposed, 0 Disagree *(6/8/07 AM)*

***Vote*: 16 Agree, 2 Not Opposed, 1 Disagree**

NOT APPROVED

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (FACDQ)

Teleconference Meeting

1-866-299-3188

202-566-1045#

August 28, 2007, 1 PM to 4 PM EDT

Decisions at Meeting #9

NONE

APPENDIX A: Committee Charter

APPENDIX A: Committee Charter

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs

Meeting #10

FDIC Seidman Center, Rooms 203 & 205

3501 Fairfax Drive, Arlington, VA

Wednesday – Friday, September 19-21, 2007

Draft Decisions at Meeting #10

*Note: Shaded votes are straw polls and not official votes taken by the Committee. The presentation reflects the order the recommendations were considered and voted on during the meeting.

1. Groundrules Amendment

The FACDQ agrees to amend the groundrules to include the following new and modified language:

In the absence of consensus, the committee will report its results as follows:

If the committee is evenly split, the committee will report different perspectives held on the issue, the rationale behind the perspectives, and the number of votes cast for each perspective.

If the voting tally shows a clear majority/minority split, the committee will report the majority position with perspectives and rationale and the number of votes cast and the minority position with perspectives and rationale and the number of votes cast.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

2. Meeting Summary #8

The FACDQ agrees to approve the meeting summary of Meeting #8 with the added language regarding the

following notes:

- That no transcript was prepared from this meeting
- That all perspectives offered at the meeting are not reflected in the meeting summary.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

3. Meeting Summary #9

The FACDQ agrees to approve the meeting summary of Meeting #9 with the added language regarding the following notes:

- That no transcript was prepared from this meeting
- That all perspectives offered at the meeting are not reflected in the meeting summary.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

4. Uses Recommendations

A. Use #6 - Great Lakes Initiative (GLI)

The FACDQ agrees to approve Use #6 - Great Lakes Initiative (GLI) of the Uses Document as follows:

Recommendation: The FACDQ recommends that the FACDQ recommendations should not supersede the current Great Lakes Initiative provisions. The FACDQ believes that there is not a significant conflict between the FACDQ recommendations and the Great Lakes Initiative.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

B. Use #7 - Other Uses to Consider

The FACDQ agrees to approve Use #7 - Other Uses to Consider of the Uses Document as follows:

Decision: The FACDQ tabled the discussion on specific recommendations regarding the use of detection and quantitation for other uses including, but not limited to, the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization
- reasonable potential analysis
- effluent guidelines development
- limit derivation
- development of water quality criteria

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

C. Use #8 - Alternative Test Procedures

The FACDQ agrees to approve Use #8 - Alternative Test Procedures of the Uses Document as follows:

Recommendation: The FACDQ did not develop specific recommendations to EPA on updating the Alternative Test Procedures (ATP) Program. The FACDQ, however, does recommend that the ATP Program be updated to be consistent with recommendations from this document.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

D. Moving Use #1-#3 from the Uses Document

The FACDQ agrees to remove Uses #1-#3 from the Uses Document.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-20-07)*

APPROVED

E. ICIS Language

The FACDQ agrees to remove the following language from two places in Use #5 in the Uses Document:

"for purposes of updating 40 CFR Part 136 National Quantitation Limits."

Vote*: 16 Agree (Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Nan T., Roger C., Larry L., John P., Dave P., David K., Michael M., Rick R., Barry S., Mary S.*), 3 Not Opposed (***Cary J., Chris H., Jim P.*), 0 Disagree, 1 Absent (***Zonetta E.*) *(9-20-07)*

APPROVED

F. Promulgation of QL_{nat}

The FACDQ recommends that EPA promulgate a QL_{nat} with the following minimum requirements:

1. EPA will use the DQO process to set MQO target MQOs for NPDES permit compliance testing.
2. A minimum of 6-7 labs.
3. Data collected at a minimum over 3- 6 months.
4. A minimum of 20 QL spikes used in the calculation of each single lab limit.
5. The data and lab be evaluated for validity prior to acceptance.
6. An appropriate outlier test is then applied to the dataset.
7. Evaluate the data for normality, using standard statistical tests.
8. If the data is normally distributed then calculate the upper 95% confidence limit, which becomes the $QL_{nat.}$
9. If the data is non-normally distributed then the 95^{th} percentile QL_{lab} becomes the $QL_{nat.}$
10. EPA should then promulgate the newly calculated QL_{nat}.

***Straw Vote*: 8 Agree, 10 Not Opposed, 1 Disagree, 1 Abstain** *(9-20-07)*

G. Promulgation of QL_{nat}s for Existing and Future Methods (Formerly Use #4)

The FACDQ recommends that:

1. QL_{nat}'s be promulgated in a Part 122 table by analyte

2. EPA generate QL_{nat}s as rapidly as possible so that recommendation #TBD (current section 5 of the Uses Document) can be fully implemented.

3. QL's be promulgated only using the nationally promulgated approach.

4. Methods may be promulgated without promulgating a QL for that method. As new methods are proposed without a promulgated QL, data (eg: Single Lab Detection, Single Lab Quantitation, etc.) showing demonstrated method performance should be included in the method. The methods should include a statement that these performance levels are guidance and may not always be achievable.

Vote*: 16 Agree, 4 Not Opposed (Cary J., Nan T., Zonetta E., Chris H.*), 0 Disagree** *(9-20-07)*

APPROVED

H. Promulgation of QLs

The FACDQ recommends the following criteria be considered when EPA proposes the procedure for determining a QL:

1. EPA will use the DQO process to set target MQOs for NPDES permit compliance testing.

2. A minimum of 6-7 labs.

3. Data collected at a minimum over 3- 6 months.

4. A minimum of 20 QL spikes used in the calculation of each QL_{lab}.

5. The data and lab be evaluated for validity prior to acceptance.

6. An appropriate outlier test is then applied to the dataset.

7. Evaluate the data for normality, using standard statistical tests.

8. If the data is normally distributed then calculate the upper 95% confidence limit, which becomes the QL.

9. If the data are non-normally distributed then the 95^{th} percentile QL_{lab} becomes the QL.

Vote*: 9 Agree (Tom M., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P.*), 8 Not Opposed (***Dave A., Bob A., Steve B., Richard B., Cary J., Nan T., Michael M., Rick R.*), 1 Disagree (***Mary S.*), 2 Absent (***Tim F., Barry S.*) *(9-20-07)*

NOT APPROVED

I. Use #5 Setting Permit Conditions, Reporting and Using Data, and Determining Compliance When the Water Quality Based Effluent Limit (WQBEL) is Less Then Detection and Quantitation Capabilities of Existing Methods

The FACDQ recommends that EPA implement Section #5 of the Uses Document as follows:

Recommendation: The FACDQ recommends that the following recommendations be incorporated into 40 CFR Part 122, as appropriate.

A. Recommendations for NPDES Permit and Compliance Uses When a National Quantitation Limit Exists

If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B.

1. **Permit Requirements Related to Detection and Quantitation**

   Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122:

   1. The default quantitation limit to be included in the permit or in rule as appropriate (Permit Quantitation Limit) is the Part 122 promulgated National Quantitation Limit unless the regulator determines that the Permit Quantitation Limit should be adjusted to account for sensitivity, selectivity, and/or matrix effects;

   2. The permit shall contain a condition that the quantitation limit determined by the permittee's laboratory (Laboratory Quantitation Limit) shall be at or below the Permit Quantitation Limit. The permittee's laboratory may use any Part 136 method for which they can demonstrate a Laboratory Quantitation Limit at or below the Permit Quantitation Limit. If matrix effects have been given special attention in the permit then they would also have to be considered in compliance and enforcement.

3. The permit shall require the permittee to report the detection limit (Laboratory Detection Limit) and the Laboratory Quantitation Limit and maintain such information for a period of at least five years;

4. The permit shall require the permittee to maintain individual numeric results for a period of at least five years. The regulator may require the individual numeric result for any value that is greater than or equal to the Laboratory Detection Limit and less than the Permit Quantitation Limit be reported in a supplemental report.

5. The permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;

6. That EPA require the Laboratory Detection Limit, the Laboratory Quantitation Limit, and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS).

2. **Establishing Compliance Thresholds and Determining Compliance**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122:

1. Regulators will set average and daily maximum permit limits at the WQBEL.

2. Permittees must report to the regulator all information in the following manner on the Discharge Monitoring Report (DMR):

    i. To report daily maximum sample results:

    1. For values not detected at the Laboratory Detection Limit, report “not detected”.

    2. For values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit, report “detected less than the Permit Quantitation Limit”.

    3. For values greater than or equal to the Permit Quantitation Limit, report the actual numeric values.

    i. To report average sample results:

1. When all values used to calculate an average are not detected at the Laboratory Detection Limit, report "not detected".

2. When all values used to calculate an average are "detected less than Permit Quantitation Limit," report "detected less than the Permit Quantitation Limit."

3. When values used to calculate an average are a combination of "not detected" and "detected less than the Permit Quantitation Limit", report "detected less than the Permit Quantitation Limit".

4. When any value used to calculate an average is greater than or equal to the Permit Quantitation Limit, report the calculated numeric average after assigning zero to any individual value reported either as "not detected" or "detected less than the Permit Quantitation Limit."

    3. To determine NPDES permit compliance with results reported on the DMR, regulators will:

        i. Determine that any daily maximum or monthly average results reported as either "not detected" or "detected less than the Permit Quantitation Limit" are in compliance with the effluent limitation.

        ii. Compare any numeric results directly to the WQBEL

3. **Additional Permit Requirements**

    Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122: Permits shall include language that triggers additional steps when a "significant number" (to be determined in permitting process) of values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported on the DMR.

B. Recommendations for NPDES Permits and Compliance Uses When No National Quantitation Limit Exists, or if the Permitting Authority Requires a Permit Quantitation Limit lower than the National Quantitation Limit.

Recommendations:

1. In the absence of a National Quantitation Limit, the permitting authority is free to establish its process for determining compliance for analytes that have limits/water quality standards at a level lower than that which can be detected and/or quantified.

2. For a list of analytes as defined by EPA, the permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136

procedure to establish the lowest possible value by the laboratory;

3. That EPA require the Laboratory Detection Limit and the Laboratory Quantitation Limit and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS).

Vote*: 12 Agree (Dave A., Bob A., Tom M., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Mary S.*)**, 4 Not Opposed (***Tim F., Richard B., Nan. T., Cary J.*)**, 4 Disagree (***Steve B., Michael M., Rick R., Barry S.*)** *(9-21-07)*

NOT APPROVED

5. Additional Recommendations

A. Additional Recommendation #3

The FACDQ agrees to approve the following Additional Recommendation:

"EPA continue to act as the national lead for Clean Water Act (CWA) programs in developing analytical methods and setting the performance standards for those methods."

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

B. Additional Recommendation #4

The FACDQ agrees to approve the following Additional Recommendation:

"EPA evaluate the federal resources dedicated to developing analytical methods with detection/quantitation limits of sufficient quality (i.e., meet data quality objectives) and capable of meeting the needs of CWA programs (e.g., quantitation at or below current water quality standards) and adjust those resources, where necessary, to meet data quality and program needs."

Vote*: 19 Agree, 0 Not Opposed, 0 Disagree, 1 Abstain (Mary S.*)** *(9-19-07)*

APPROVED

C. Additional Recommendation #7

The FACDQ agrees to approve the following Additional Recommendation:

"EPA develop and implement guidance on the new procedures as well as a computer-based program to assist in calculating detection and quantitation limits."

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

D. Additional Recommendation #1

The FACDQ agrees to approve the following Additional Recommendation:

"To maintain consistency and minimize effects on the environmental laboratory community, the FACDQ recommends that EPA programs that reference the present Part 136 Appendix B procedure consider adopting (the new procedure) that would replace it."

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

E. Additional Recommendation #2

The FACDQ agrees to approve the following Additional Recommendation:

"The FACDQ recommends that EPA's Office of Water complete a follow up pilot study to confirm the performance of the procedure(s) proposed for promulgation."

Vote*: 17 Agree, 3 Not Opposed (Tom M., Steve B., David K.***), 0 Disagree** *(9-19-07)*

APPROVED

F. Additional Recommendation #5

The FACDQ agrees to approve the following Additional Recommendation:

"EPA evaluate and modify the uses of data in CWA programs (beyond those uses discussed in the FACDQ recommendations) based on data uncertainty and decision error rate requirements relative to corresponding detection and quantitation limits. This could be accomplished through establishment of and adherence to data quality objectives for all CWA programs. How data relative to detection and quantitation limits are to be used in 303(d) listings, reasonable potential determinations, NPDES effluent limit derivation, the development of water quality criteria, and other uses should be documented."

Vote*: 13 Agree (Dave A., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Michael M., Rick R., Barry S.*)**, 6 Not Opposed (***Bob A., Tim F., Tom M., Steve B., Richard B., Cary J.*)**, 1 Disagree (***Mary S.*)** *(9-20-07)*

NOT APPROVED

G. Additional Recommendation #6

The FACDQ agrees to approve the following Additional Recommendation:

"EPA establish data quality objectives (with indicators and measurement quality objectives) for CWA programs where detection/quantitation limits are used in decision making."

Vote*: 15 Agree (Dave A., Bob A., Tim F., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Michael M., Rick R.., Barry S.*)**, 4 Not Opposed (***Tom M., Steve B., Richard B., Cary J.*)**, 1 Disagree (***Mary S.*)** *(9-20-07)*

NOT APPROVED

H. Peer Review of the Procedure

The FACDQ recommends that a formal peer review take place for the FACDQ recommended procedure.

Vote*: 16 Agree, 4 Not Opposed (Bob A., Nan T., Zonetta E., Jim P.*)**, 0 Disagree** *(9-20-07)*

APPROVED

6. Single Lab Procedure Recommendations

A. Lab-Determined Detection Limits and Quantitation Limits (*As Is*)

The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure v2.4[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

1 The FACDQ recognizes that EPA cannot commit to promulgate the recommendations of the FACDQ without the benefit of public notice and comment. Wherever "promulgate" appears in the FACDQ recommendations, the FACDQ expects that EPA will propose a rule consistent with the FACDQ recommendations and then finalize a rule that fully considers those public comments.

2 This procedure was created via modifications to the ACIL.

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

***Straw Vote*: 9 Agree, 8 Not Opposed, 3 Disagree,** *(9/20/07)*

B. Lab-Determined Detection Limits and Quantitation Limits (*With Quick Resolution on Modifications*)

*Note: This vote reflects the Committee's desire to explore potential modifications and spend time on the language below:

The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure v2.4[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

***Straw Vote*: 10 Agree, 8 Not Opposed, 2 Disagree** *9/20/07)*

C. Optional Batch Specific Verification

The FACDQ recommends that the following language be moved into the DQFAC Single Lab Procedure v2.4:

Blanks and QL spikes in each batch

1. If the method blank exceeds the DL and a cause cannot be identified, raise the DL to the blank result for future analysis

2. If the QL spike result (or QL spike times QL/spike level, if not spiking exactly at the QL) is less than the DL, elevate the QL by a factor of two and repeat the QL spike at the new QL. Repeat this until the QL spike is at or above the DL.

3. If the QL spike result is outside the average specified accuracy, elevate the QL by a factor of two and repeat the QL spike at the new QL. Repeat this until the QL spike meets the specified accuracy criteria.

Vote*: 4 Agree (Zonetta E., Chris H., Jim P., David K.***), 9 Not Opposed (***Richard B., Cary J., Nan T., Roger C., Larry L., John P., Dave P., Rick R., Barry S.***), 7 Disagree (***Dave A., Bob A., Tim F., Tom M., Steve B., Michael M., Mary S.***)** *(9-20-07)*

NOT APPROVED

D. Batch Verification

The FACDQ recommends that during promulgation, EPA include and/or develop language to incorporate batch specific verification as an option in the procedure.

Vote*: 16 Agree, 4 Not Opposed (Tom M., Richard B., Cary J., Mary S.*)**, 0 Disagree** *(9-20-07)*

APPROVED

E. QL Verification Frequency

The FACDQ recommends that the following be adopted into the DQFAC Single Lab Procedure v2.4:

Section 2.10 of the ACIL procedure specifies monthly QL verification spikes, evaluated on a quarterly basis. Section 2.2 of revised ACIL procedure specifies a minimum of quarterly QL verification spikes, evaluated on an annual basis. If we went to monthly QL verification spikes, evaluated annually this would provide a minimum of 24 QL spikes over a two year period to generate the long term estimate:

2.2 Continue to collect method blanks with each batch from which data were reported and QL spikes for every analyte[1] analyzed at least monthly (or four per twelve month period in separate batches spread across the time period during which analysis is conducted) which ever is greater. If multiple instruments are to be used for reporting data with the same DL and QL, analyze two to six QL spikes per instrument per twelve month period, so that a minimum of twelve QL spikes are generated each year.

2.2.1. Evaluate your DLs and QLs at least every year using all of the spikes available in a 24 month period using the procedures described in the Sections below. All method blanks and QL spikes collected within a 24 month period should be used for reassessing DLs and QLs, unless there is reason to believe that the DL or QL changed substantially at some point during that 24 month period. In that case the most recent data may be used for the reassessment, but not less than 20 method blanks and seven QL spikes per instrument.
Vote*: 4 Agree (Roger C., Larry L., John P., Dave P.*)**, 5 Not Opposed (***Zonetta E., Chris H., David K., Jim P., Rick R.*)**, 11 Disagree (***Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Cary J., Nan T., Michael M., Barry S., Mary S.*)** *(9-20-07)*

1 For multi component analytes a lab may use representative analytes to collect data for classes of compounds. When a representative analyte is monitored, the other analytes that compound represents must have similar sensitivity and method performance characteristics as demonstrated in initial DL/QL studies. If DLs or QLs for a monitored analyte are adjusted, as a consequence of on-going verification, the same adjustment must be applied to all analytes represented. An example is method 608 which includes several Aroclors, Toxaphene, and technical Chlordane. In this case, a mixture of Aroclors 1016 and 1260 might be used to represent all Aroclos. Toxaphene may be used to represent both Toxaphene and technical Chlordane.

NOT APPROVED

F. QL Verification Frequency

The FACDQ recommends that EPA give additional consideration to increasing the frequency of QL verification and report its findings in the preamble of the Federal Register Notice and request specific comments on the final proposed frequency.

Vote*: 11 Agree, 9 Not Opposed (Bob A., Tim F., Tom M., Steve B., Richard B., Cary J., Nan T., Michael M., Mary S.***) 0 Disagree** *(9-20-07)*

APPROVED

G. DL Verification and Recalculation

The FACDQ recommends that the following be adopted into the DQFAC Single Lab Procedure v2.4:

Section 1.9 of the ACIL procedure specifies annual recalculation of DL and then uses an F test to determine if the DL should be revised. Section 2.2.2 (now 2.4) allows optional recalculation of the DL, with no decision criteria provided. By making the recalculation of the DL optional it is possible that the false positive error rate using the parametric statistical test could be greater than 1%.

2.2.2 Recalculate the DL using the formulas in 1.1.7. or 1.2.7.

Vote*: 8 Agree (Dave A., Roger C., Larry L., John P., Dave P., Zonetta E., David K., Jim P.***), 10 Not Opposed (***Bob A., Tom M., Steve B., Richard B., Cary J., Nan T., Chris H., Michael M., Rick R., Barry S.***), 2 Disagree (***Tim F., Mary S.***)** *(9-20-07)*

NOT APPROVED

H. Lab-Determined Detection Limits and Quantitation Limits

The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure v2.4[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

Vote*: 14 Agree (Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Nan T., Roger C., Larry L., John P.,*

Dave P., Zonetta E., Jim P., Rick R.), **1 Not Opposed (***Chris H.*), **5 Disagree (***Cary J., David K., Michael M., Barry S., Mary S.*) *(9-20-07)*

NOT APPROVED

7. Target MQO Bounds Recommendation

The FACDQ recommends that a single set of MQO bounds be established for promulgated Part 136 methods that define Quantitation for CWA compliance and enforcement uses.

Vote*: 7 Agree (Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P.*), **3 Not Opposed (***Dave A., Bob A., Tim F.*), **8 Disagree (***Tom M., Steve B., Cary J., Nan T., Michael M., Rick R., Barry S., Mary S.*), **2 Absent (***Roger C., Richard B.*) *(9-21-07)*

NOT APPROVED

8. Matrix Effects Recommendations

A. Recommendation #1

The FACDQ recommends that EPA publish new guidance on matrix effects. At a minimum, the guidance should outline the appropriate level of matrix effects validation necessary for method promulgation for analytical methods to be considered for 40 CFR Part 136. The FACDQ recommends that EPA adhere to this guidance in methods it develops and validates for promulgation in 40 CFR Part 136. This guidance should also address the following:

- Determining the appropriate number of matrices to take into account.
- The level of validation required verses the proposed scope of use for the analytical method.
- Matrix effects validation in the ATP program.
- Impacts for consensus standards methods considered for part 136.

Vote*: 10 Agree (Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Barry S.*), **7 Not Opposed (***Dave A., Bob A., Tim F., Tom M., Cary J., Michael M., Rick R..*), **3 Disagree (***Steve B., Richard B., Mary S.*) *(9-21-07)*

NOT APPROVED

B. Recommendation #2

The FACDQ recommends that EPA develop a consistent protocol on how to demonstrate matrix effects. The FACDQ believes such a protocol should be sensitive to cost and required level of effort to ensure that it is applied consistently.

Questions to be addressed by the protocol:

- What level of effort is necessary to determine if the matrix effects can be resolved by modifications of the analytical method that are within the flexibility allowed within the method?
- What set of experiments and data interpretation framework would suffice to demonstrate a matrix effect if performed properly?
- Who should be responsible for implementing a procedure to determine a matrix specific QL?
- How broadly applicable shall a matrix effect be considered? What level of demonstration should be considered adequate for a single facility? What level of demonstration should be undertaken to extend the matrix specific QL to other like wastewaters?

Vote*: 13 Agree (Dave A., Bob A., Tom M., Richard B., Nan T., Roger C., Larry L., Dave P., John P., Zonetta E., Chris H., Jim P., Rick R.***), 6 Not Opposed (***Tim F., Steve B., Cary J., David K., Michael M., Barry S.***), 1 Disagree (***Mary S.***)** *(9-21-07)*

NOT APPROVED

C. Recommendation #3

The FACDQ recommends that EPA develop a procedure for determining matrix-specific detection or quantitation limits for use where appropriate. Again, such a protocol should be sensitive to cost and required level of effort.

Questions that should be addressed include:

- Who should be responsible for implementing a procedure to determine a matrix specific QL?
- How broadly applicable shall a matrix effect be considered?

  What level of demonstration should be considered adequate for a single facility?

  What level of demonstration should be undertaken to extend the matrix specific QL to other like wastewaters?

Vote*: 11 Agree (Dave A., Tom M., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., Jim P.***), 8 Not Opposed (***Bob A., Tim F., Steve B., Cary J., David K., Michael M., Rick R., Barry S.***), 1 Disagree (***Mary S.***)** *(9-21-07)*

NOT APPROVED

D. Recommendation #4

When considering future updates of QL_{nat}, the FACDQ recommends that EPA take into consideration any experience with the performance in different matrices when considering a revision of the QL_{nat}.

Vote*: 11 Agree (Dave A., Tom M., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., Jim P.*)**, 4 Not Opposed (***David K., Michael M., Rick R., Barry S.*)**, 5 Disagree (***Bob A., Tim F., Steve B., Cary J., Mary S.*)** *(9-21-07)*

NOT APPROVED

9. Verification Recommendation

The FACDQ recommends that the Verification Document be used as a resource document for the Single Lab DL QL Procedure v2.4 majority/minority report.

Vote*: 18 Agree, 2 Not Opposed (Zonetta E., Chris H.*)**, 0 Disagree** *(9-21-07)*

APPROVED

10. Implementation Recommendations

A. Recommendation #1

Although the FACDQ did not reach consensus on a procedure, we recommend that EPA act to develop an alternative to the current 40 CFR Part 136 Appendix B procedure. The results of the pilot study, and our evaluation of the ACIL modified procedure, indicate that there are deficiencies in the current 40 CFR Part 136 Appendix B procedure that can and should be corrected. The Single Lab DL QL Procedure v2.4 submitted contains elements that would be valuable to the agency in developing a new procedure.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-21-07)*

APPROVED

B. Recommendation #2

The FACDQ recommends that EPA develop guidance and outreach materials for stakeholders as EPA implements the FACDQ recommendations.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-21-07)*

APPROVED

11. Definitions Recommendations

A. Recommendation #1

The FACDQ recommends adding the IUPAC L_C, L_D, and L_Q definitions into the glossary.

Vote*: 13 Agree, 6 Not Opposed (Bob A., Tim F., Tom M., Richard B., Cary J., David K.*)**, 0 Disagree, 1 Absent (***Dave A.*)** *(9-21-07)*

APPROVED

B. Definitions: Detection Limits

The FACDQ recommends that the definitions for Detection Limits below be adopted for use in the Final Report:

DETECTION LIMIT (DL) – LAYPERSON'S DEFINITIONS

1. **Detection Limit (DL) -** The minimum result which can be reliably discriminated from a blank (for example, with a 99% confidence level).

2. **Detection Limit (DL)** – The lowest result that can be distinguished from the blank at a chosen level, α, of statistical confidence.

DETECTION LIMIT (DL) - STATISTICAL DEFINITIONS

1. **Detection Limit (DL)** - Smallest measured amount or concentration of analyte in a sample that gives rise to a Type I error tolerance of alpha under the null hypothesis that the true amount or concentration of analyte in the sample is equal to that of a blank. (The alternative hypothesis is that the true amount or concentration of analyte is greater than that of a blank.)

2. **Detection Limit (DL)** - The minimum observed result such that the lower 100 (1-)% confidence limit on the result is greater than the mean of the method blanks.

Vote*: 12 Agree, 7 Not Opposed (Steve B., Cary J., Zonetta E., Chris H., David K., Jim P., Mary S.*)**, 0 Disagree, 1 Absent (***Barry S.*)** *(9-21-07)*

APPROVED

C. Definitions: Quantitation Limits

The FACDQ recommends that the definitions for Quantitation Limits below be adopted for use in the Final Report:

QUANTITATION LIMIT (QL) - DEFINITIONS

1. **Quantitation Limit (QL)**: The smallest detectable concentration of analyte greater than the detection limit (DL) where the accuracy (precision & bias) achieves the objectives of the intended purpose.

2. **Lab Quantitation Limit (QL_{lab})**: The smallest detectable concentration of analyte greater than the detection limit (DL) where the accuracy (precision & bias) demonstrated by the laboratory achieves the objectives of the intended purpose.

Vote*: 3 Agree (*John P., Rick R., Mary S.*), 16 Not Opposed, 0 Disagree, 1 Absent (*Barry S.*) *(9-21-07)

APPROVED

12. Final Report Recommendation

The FACDQ approves the proposed process and schedule below for the Final Report of the Committee's work.

- The lead for each section will work with the designated back-ups to draft that section.
- The Final Report Work Group has some discretion over what goes into the appendices.
- As soon as a section is drafted, the lead will circulate it electronically to the caucuses for review and comment on a quick turn-around basis.
- Reviewers will be asked to send their comments on the initial draft via "tracked changes."
- The drafting team for each section will address those comments to the extent possible, accepting or rejecting the comments or making appropriate revisions, eliminating the "tracked changes."
- Before sending the draft to the Final Report Work Group, the lead will highlight any unresolved issues for Final Report Work Group discussion in **bold** type.
- The Uses Document was not a consensus document and it should be indicated as such in the main report with majority/minority perspectives.

APPENDIX A: Committee Charter

- The Uses Document will be modified and included in the Appendix and will reflect the decisions made at the 10th FACDQ Meeting prior to being presented for a vote:
    - Moving Uses #1-#3 outside of the document.
    - The edits made on #4 prior to being voted on.
    - The edits to #5 prior to being voted on.

Proposed Schedule

- October 5: Majority/Minority Reports due to leads for the relevant section in the report
- November 9: Final Report Work Group sends first draft to the committee
- November 19: Submit comments back to Final Report Group.
- November 30: Final Report Work Group sends revised draft to the committee.
-

Details

- Use Microsoft Word, Times New Roman, font size 12
- Put section number and name in footer with the date of the draft (not autodates)
- Be precise about references; credit those that are used.

Vote*: 17 Agree, 0 Not Opposed, 0 Disagree, 3 Absent (Barry S., Jim P., Steve B.*) *(9-21-07)***

APPROVED

APPENDIX C:

What We Need A Procedure To Do

Adopted by Consensus on July 13, 2006

By the Federal Advisory Committee on Detection and Quantitation Approached and Uses in Clean Water Act Programs

Introduction

At its December 8-9, 2005 meeting, the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs (FACDQ, committee) agreed by consensus that its recommendations concerning analytical procedures for detection and quantitation in Clean Water Act programs should be based on what members of the advisory committee need procedures to do.

Members of the committee discussed what they needed procedures to do in the ensuing months in Policy Work Group meetings, with additional input from the Technical Work Group. At its March 29-30, 2006 meeting, the committee reviewed a draft document, "What do we need a procedure to do," which identified 13 objectives. After discussion, the committee agreed to the 13 objectives and added a 14th. The committee also agreed that the objectives would apply to long-term committee recommendations, but that the setting of any numeric objectives (i.e. false positive, false negative, precision and accuracy) would apply only to the pilot study.

Individual caucuses then reviewed the draft document, including how each objective would be evaluated, and provided comments. The facilitators consolidated the comments into a revised document. The committee created a subgroup, consisting of Bob Avery, Richard Burrows, Michael Murray, John Phillips and Jim Pletl, and asked it to consider the caucus comments and to refine the 14 objectives and ways to measure them as input into the pilot study design.

The subgroup held a two-hour call on Monday, April 24 to review the objectives and to revise the document in light of the comments. In carrying out this assignment, the subgroup noted the following:

- The objectives defined in the document are intended to be used to evaluate procedures tested in the pilot study. The committee does not expect that procedures will meet all of these objectives. After receiving the pilot study results, the FACDQ may decide to revisit the objectives or it may seek to

revise the procedures so they better meet the objectives.

- The committee acknowledged that cost and contracting restraints are factors that will affect the pilot study. To the maximum extent possible, the pilot will be conducted using a wide range of labs and methods.

- The committee agreed to specific measurement quality objectives (MQOs) for false positives, false negatives, and precision to be used in the pilot study. For accuracy (bias), the committee assigned the Technical Work Group and Pilot Design Team to establish values based on the specific analytical methods accuracy levels and existing data.

Committee approval and intent

The Committee again reviewed the document at its July 13-14, 2006 meeting, added an objective, and adopted the document by consensus. The committee generally agreed that the list of characteristics should be built with the final recommendations in mind and that those objectives should drive the pilot study to test whether procedures met those objectives. Committee members also generally agreed that the pilot test was an opportunity to inform the committee's final recommendation and that some of the objectives might be refined as a result of the pilot study data.

The fifteen objectives

The remainder of this document identifies the 15 objectives for testing procedures and suggests how each objective could be evaluated as part of the pilot test. The term "limit" is used generally to refer to detection and quantitation limits since the FACDQ has not yet defined them. Examples of how to measure specific objectives are sometimes written broadly and may not apply in every case (L_C, L_D, L_Q, other).

The procedure(s) will:

1. **provide an explicit estimate of bias at L_Q for limits that must be verifiable by labs at those limits.**

To be evaluated by:

1. reviewing procedure(s) and specifically identifying the quantitative limit for bias at L_Q that is tested in the pilot study.

2. requiring labs to analyze samples (spikes, blind or otherwise as appropriate) and comparing observed bias to that cited by the procedure(s).

See Appendix for specific MQOs adopted by the committee for the pilot study

2. **provide an explicit estimate of precision at L_Q for limits that must be verifiable by labs at those limits.**

To be evaluated by:

1. reviewing procedure(s) and specifically identifying the quantitative limit for precision at L_Q that is tested in the pilot study.

2. requiring labs to analyze samples (spikes, blind or otherwise as appropriate) and comparing observed precision to that cited by the procedure(s).

See Appendix for specific MQOs adopted by the committee for the pilot study

3. **provide an explicit false positive rate for L_C.**

To be evaluated by:

1. reviewing procedure(s) and specifically identifying the false positive error rate predicted for each limit that is tested in the pilot study.

2. comparing the false positive rate of lab blanks at the estimated levels of L_C to those predicted by the procedure(s).

Note: *The intent is to look at long term performance, however for the pilot study the number of samples may be relatively small.*

See Appendix for specific MQOs adopted by the committee for the pilot study

4. **provide an explicit false negative rate at L_C for the true value at L_D or L_Q that must be observed in labs at L_C for the estimated values of L_D or L_Q.**

To be evaluated by:

1. reviewing procedure(s) and specifically identifying the false negative error rate predicted for L_D/L_Q that is tested in the pilot study.
2. comparing the false negative rate of results obtained by analyzing samples spiked at the L_D/L_Q concentration to those predicted by the procedure(s).

Note: *The intent is to look at long term performance, however for the pilot study the number of samples may be relatively small.*

See Appendix for specific MQOs adopted by the committee for the pilot study

5. **provide that qualitative identification criteria defined in the analytical method are met at the determined detection and quantitation limits.**

To be evaluated by:

1. requiring that all method qualitative identification criteria be satisfied in order for detection to occur.
2. requiring revision of L_Q or L_D if all spikes at L_Q or L_D are not detected.

6. **adequately represent routine variability in lab performance**.

To be evaluated by determining whether the procedure(s):

1. use data to calculate limits that are collected over enough time to capture variability in performance relative to MQOs.
2. incorporate variability due to the use of multiple instruments per lab.

3. incorporate variability due to the use of multiple analysts per lab.
4. incorporate variability occurring across laboratories (not for single lab procedure).
5. adjust or account for recovery.
6. provide recommendations or limit choices for outlier tests.
7. address varying numbers of different concentrations (spikes) that can be used among laboratories (may only apply to multi/inter lab procedures).
8. address varying numbers of replicates per concentration (spike) that can be used among laboratories (may only apply to multi/inter lab procedures).
9. address varying combinations of concentrations (spikes) that can be used among laboratories (may only apply to multi/inter lab procedures).
10. adequately accommodate different models of instruments used per analyte and corresponding technology used to calculate limits.

7. **perform on-going verification of estimates.**

   To be evaluated by:

   1. continuously analyzing periodic blanks to assess the estimate of L_C.
   2. continuously analyzing periodic low-level spike samples near L_Q to assess the estimate of L_Q.
   3. recalculating limits at a frequency that captures variability in performance relative to MQOs.

8. **be capable of calculating limits using matrices other than lab reagent grade water.**

To be evaluated by:

1. reviewing procedure(s) and determining that there is nothing precluding the use of matrices other than reagent grade water to calculate limits.
2. reviewing procedure(s) to determine if they incorporate steps to verify when limits adopted for

an analytical method can or cannot be met in a matrix other than lab reagent grade water.

3. reviewing procedure(s) to determine if they provide instructions on preparing an analyte-free matrix that approximates the matrix in question.

9. **use only data that results from test methods conducted in their entirety.**

To be evaluated by determining whether the procedure(s):

1. require that samples used to calculate detection and quantitation limits undergo all routine steps outlined in an analytical method as specified in the laboratory's SOP (prep method, extraction, etc.).

2. reviewing procedure(s) to determine if they incorporate steps to verify when limits adopted for an analytical method can or cannot be met when a sequence of non-routine steps are used.

10. **explicitly adjust or account for situations where method blanks always return a non-zero result/response.**

To be evaluated by:

1. reviewing procedure(s) and determining if they include a process to address occasions when method blanks always return a non-zero result.

2. reviewing procedure(s) and determining if they require calculation of statistics regarding non-zero results/responses.

3. reviewing procedure(s) and determining if they mathematically adjust limits for non-zero results/responses.

11. **explicitly adjust or account for situations where method blanks are intermittently contaminated.**

To be evaluated by:

1. reviewing the procedure(s) and determining if they define intermittent contamination and provide explicit instructions to deal with this situation.

2. reviewing the procedure(s) and determining if they mathematically adjust limits for non-zero results/responses.

12. **be clearly written with enough detail so that most users can understand and implement them.**

To be evaluated by:

1. asking users to interpret data prior to the after-procedure calculations are carried out. Examples include: What is the resulting detection limit? What is the resulting quantitation limit? What is the blank bias?

2. asking users questions about the procedure characteristics and the use of the matrix as a point of reference. Examples include: Do the procedures address recovery? How often is a limit calculated by the user? How often is data generated to calculate limits for a given procedure?

3. asking users to perform calculations or run software and interpret results.

4. asking users to select spikes for given circumstances.

5. reviewing procedure(s) and determining which ones minimize the amount of data required to calculate analytical limits beyond that normally generated by analytical methods.

6. determining that the procedure(s) do not require skills of users in addition to those that are normally required by laboratories.

13. **be cost effective.**

To be evaluated by:

1. reviewing procedure(s) and determining which ones minimize the amount of data required to calculate analytical limits beyond that normally generated by analytical methods.

2. determining whether the procedure(s) require the purchase of software or equipment in

addition to that which is normally required by laboratories.

3. determining that the procedure(s) do not require skills of users in addition to those that are normally required by laboratories.

14. **assess multi- and inter-laboratory variability when data from more than one lab is used.**

To be evaluated by:

1. comparing results from multi-, inter-, and single lab studies.
2. Calculating intra-lab, inter-lab, and pooled or multi-lab variability and the associated variance error components.

15. **be applicable to all users and test methods.**

To be evaluated by:

1. testing procedure(s) against objectives 1-13 among a representative sample of labs (states, EPA, commercial, municipal, small, medium and large, etc.).
2. testing procedure(s) against objectives 1-13 among a representative sample of analytical test methods (different technologies and analytes).

APPENDIX D:

DQ FAC Single Laboratory Procedure v2.4

8/30/2007

SCOPE

Procedures are provided by which an individual laboratory may derive accurate estimates of routine method sensitivity for most analytical methods.

These procedures set the Detection Limit (DL) at the lowest result that can be reliably distinguished from a blank (specifically a false positive rate of ≤ 1% is targeted). This is conceptually equivalent to the IUPAC term Critical Value, L_C. The DL is the normal censoring limit for analytical result reporting.

The Quantitation Limit (QL) is set at the level that meets specific criteria that are defined within this procedure.

The procedure requires that the specification of the precision and accuracy (measured as recovery of spikes) required for the intended use of the method be identified. The limits required may come from the analytical method, regulatory documents, or be set by the laboratory based on method performance if not available from these sources. The procedure requires that these criteria must be satisfied from samples spiked at or close to the QL

The lowest calibration standard (or low level calibration verification standard for tests with a single point initial calibration) must be at or below the QL. A false negative rate of ≤ 5% for a true concentration at the QL is targeted.

The QL is based on elements of the both the detection limit (Ld) and the quantitation limit (Lq) using international terminology.

This procedure is not applicable to analytical methods for which it is not feasible to create spiked samples at increasing levels of concentration. For example, it does not apply to measurements of temperature or pH.

In some cases it is not necessary to report results below the quantitation limit. In these cases the

determination of the DL may be omitted and only those steps necessary to define the QL need to be followed. If the DL and the QL are both required then all steps in the procedure should be followed.

GENERAL REQUIREMENTS

This procedure should be followed for each method where a DL and QL need to be determined. In order to form reliable estimates of detection and quantitation limits, all steps in a method must be followed during the collection of blank and low level spiked sample data. A method is defined as the combination of steps that are performed on a sample. For example, preparation steps such as liquid/liquid extraction must be performed as well as analytical steps such as gas chromatography. The use of method blank data to determine detection limits is generally preferred. However, if the instrument system returns results of "Not detected" for an analyte/method combination rather than numerical results for most blanks, then low level spikes must be used as a substitute for the method blanks.

1. INITIAL STARTUP

1.1. If no historical data are available proceed to Section 1.1.1. If historical data demonstrate that 50% or more of method blanks for an analyte give a numerical result, then estimate a DL based on blanks as described in and beginning with section 1.1.3. If less than 50% of the historical method blank results give a numeric result then skip to Section 1.2. A numeric result includes positive, negative, and zero values.

1.1.1. Collect results for method blanks generated during routine operation of the method. The method blanks must go through all preparation and analysis steps of the method. A minimum of seven numerical method blank results, each from a different preparation batch, is required in order to calculate an initial estimate of the method DL. The minimum number of blanks needs to be analyzed on each instrument used to report data. If more than seven blank results are available then they should be used. In general, the greater the number of results used to create the estimate, the more accurate it will be.

1.1.2. If less than 50% of the method blank results give a numeric result then skip to Section 1.2.

1.1.3. If it is necessary to initiate analysis immediately, an estimate of the DL may be made by analyzing seven blanks in less than seven batches. This short term DL must be replaced by a DL determined from method blanks, in a minimum of seven different batches as soon as data are available in order to capture sufficient temporal variability.

1.1.4. If multiple instruments are to be used for the same test, and will have the same reporting limit or QL, a minimum of seven method blank results must be used for each instrument and a DL calculated for each instrument. If the same DL or QL is reported for multiple instruments, the laboratory shall use the highest DL for the purposes of reporting data,

1.1.5. Results associated with known errors that occurred during analysis should be discarded, or where appropriate, corrected. It is also acceptable to apply a statistically accepted outlier test, such as the removal of results more than two or three standard deviations from the mean. Results two standard deviations or less from the mean should not be removed. With the exception of known errors, this data rejection must be performed with caution, and no more than 5% of data may be rejected. Excessive rejection

of data will result in a calculated DL lower than can be supported.

1.1.6. If not all of the blanks have numerical results, but over 50% do, set the value for those blanks that do not have numerical results to zero. Calculate the sample standard deviation of the method blank results.

$$s = \sqrt{\frac{\sum_{i=1}^{n} (X_i - \overline{X})^2}{n - 1}}$$

Where:

n = the number of results used in the calculation

X_i = a result obtained from the analysis of a sample

$\overline{X}$ the mean of the results

1.1.7 Calculate the DL: $DL = \overline{X} + s K_{(n-1,0.99,0.01)}$

Where:

- $\overline{X}$ is the mean result from the method blanks

- $K_{(n-1,0.99,0.01)}$ **is a multiplier for a tolerance limit based on 99% coverage probability of 99% of the population of routine blanks and n-1 degrees of freedom. Values for K are listed in Table 1.**

Note: In the case that a negative value for $\overline{X}$ is obtained, substitute zero for $\overline{X}$ in the equation for calculation of the DL.

1.1.8. If 5% or more blank results (after outlier removal) are greater than the DL, raise the DL as follows:

- ***to the highest result if less than 30 method blanks are available.***
- ***to the next to the highest result if 30-100 method blanks are available.***
- ***to the level exceeded by 1% of the method blanks if there are more than 100.***

Only a blank that meets method specified qualitative identification criteria (where applicable) should be given a numerical result.

1.2. This section determines the DL for methods with less than 50% of blanks giving numerical results and also determines the QL for all methods.

1.2.1. If less than 50% of method blanks give numerical results then the DL is estimated using low level spiked samples. These spiked samples are also used to define the QL for all analytical methods.

1.2.2. Select the spiking level. The spiking level must be at or below the level that the laboratory intends to use as their QL for reporting. If an estimate of the DL has been made using method blanks, then the spiking level must be at least two times that DL. The laboratory may use prior experience or consideration of the signal to noise to form this estimate. All qualitative identification criteria in the analytical method must be met for spikes at the QL; (for example, identification of qualifier ions, ion ratios, etc). Where it is necessary to achieve the lowest QL possible, follow the optional procedure described in Section 1.2.2.1.

1.2.2.1 Using the laboratory's knowledge of the method, analyze spikes of the analyte(s) in blanks. Start at a measurable concentration and reduce the spike concentrations successively in steps of approximately 3 (e.g., 100, 30, 10, 3, 1 etc) until:

- signal to noise ratio is less than 3, or
- qualitative identification criteria are lost, or
- signal is lost, or
- the value is less than twice the detection limit determined in Section 1.1

Use the lowest concentration at which all the applicable criteria are met.

1.2.3. Test the selected spiking level.

1.2.3.1. Analyze at least a single spiked blank at the intended quantitation limit and carried through the entire analytical procedure

1.2.3.2. If the analyte is not detected, either because it does not yield a signal, or the result falls below a detection limit determined in Section 1.1., or qualitative identification criteria defined in the method are not achieved, repeat the test at twice the concentration used in Section 1.2.3.1.

1.2.3.3. If multiple instruments are to be used to perform the same test and the same reporting limit or quantitation limit will be used, then the test of the QL estimate must be performed on each instrument, and the highest value from all the instruments is used as the estimate.

1.2.4. Once the appropriate spiking level (which will become the QL) is selected, analyze a minimum of seven replicates, divided among at least three different preparation batches, each spiked at this level. If it is necessary to initiate analysis immediately, an estimate of the DL and QL may be made by analyzing seven QL spikes in less than three batches. The short term DL and QL must be replaced by a DL and QL determined from QL spikes in a minimum of three different batches as soon as possible.

1.2.5. If the analyte is not detected in any one of the replicates, analyze a minimum of seven replicates divided between three different preparation batches at twice the concentration. This new concentration is the QL estimate. If multiple instruments are

used to report the same QL, at least two replicates in separate batches must be analyzed on each instrument.

1.2.6. Determine the mean recovery and relative standard deviation of the QL spike results. If precision and accuracy requirements are not met, then repeat the spike at a higher concentration (resulting in a higher QL).

Relative Standard Deviation = RSD = Standard Deviation / Mean Result

1.2.6.1. Precision and accuracy limits for the QL may be found in the analytical method or in regulatory documents. If not defined in these sources the laboratory specifies their own requirements. Precision and accuracy at the QL will be expected to be somewhat worse than at the mid level, so it is not appropriate to use criteria established for mid level spikes at the QL. In the absence of other guidance the laboratory may establish precision and accuracy limits based on the performance of the initial QL spikes.

1.2.7. Estimate the DL. If the DL has been estimated using method blanks according to Section 1, skip this section and continue to Section 1.2.8. If the DL has not been estimated using method blanks (i.e., less than 50% of method blanks had numerical results) then the DL is determined according to the following equation:

$$DL = s \times t_{(n-1,1-0.99)}$$

- Where s is the standard deviation of the measured QL spike results.
- $t_{(n-1,1-0.99)}$ is the 99th percentile of a t distribution with n-1 degrees of freedom. Values for t are listed in Table 2.

Note: The lowest achievable DL may be obtained by following the optional steps in Section 1.2.2.1.

1.2.8. If 5% or more blank results (after outlier removal) are greater than the DL, raise the DL as follows:

- ***to the highest result if less than 20 method blanks are available.***
- ***to the next to the highest result if 20-100 method blanks are available.***
- ***to the level exceeded by 1% of the method blanks if there are more than 100.***

Only a blank that meets method specified qualitative identification criteria (where applicable) should be given a numerical result.

1.2.9. Estimate the Lowest Expected Result (LER) from spikes at the QL.

$$\text{LER} = \frac{\overline{X}_s * QL}{SL} + (s * t_{(n-1,1-\alpha=0.95)})$$

- Where *s* is defined in Section 1.2.7.
- Where $\overline{X}_s$ is the mean concentration result from the QL spikes.
- $t_{(n-1,1-\alpha=0.95)}$ is the 95th percentile of a *t* distribution with n-1 degrees of freedom. Values for *t* are listed in Table 1.
- *SL* is the spike level used for the QL spike sample.

1.2.10. Compare the LER to the DL. If the LER is less than the DL then the QL is raised according to the equation:

$$\mathbf{QL_{new}} = \frac{[DL + s * t_{(1-\alpha=0.95;n-1)}] * QLold}{\overline{X}_s}$$

1.2.11. Do NOT adjust the spiking level for ongoing QL verification (see Section 2) unless the spiking level is outside the range of half to twice the new QL. If qualitative identification criteria are not met at the spiking level, increase the spiking by a factor of two.

2. ONGOING VERIFICATION

2.1. At least once every 12 months, or more frequently at the discretion of the QA manager, re-evaluate the DLs and QLs.

2.2. Continue to collect method blanks with each batch from which data were reported and QL spikes for every analyte[1] at a rate of at least four per twelve month period (in separate batches) spread across the time period during which analysis is conducted. If multiple instruments are to be used for reporting data with the same DL and QL, use at least two spikes per instrument per twelve month period.

2.2.1. Evaluate your DLs and QLs at least every year using all of the spikes available in a 24 month period using the procedures described in the Sections below. All method blanks and QL spikes collected within a twelve month period should be used for reassessing DLs and QLs, unless there is reason to believe that the DL or QL changed substantially at some point during that twelve month period. In that case the most recent data may be used for the reassessment, but not less than 20 method blanks and seven QL spikes per instrument. More than twelve months worth of data may be used if there is no reason to believe that the DLs and QLs have changed.

1 For multi component analytes a lab may use representative analytes to collect data for classes of compounds. When a representative analyte is monitored, the other analytes that compound represents must have similar sensitivity and method performance characteristics as demonstrated in initial DL/QL studies. If DLs or QLs for a monitored analyte are adjusted, as a consequence of on-going verification, the same adjustment must be applied to all analytes represented. An example is method 608 which includes several Aroclors, Toxaphene, and technical Chlordane. In this case, a mixture of Aroclors 1016 and 1260 might be used to represent all Aroclos. Toxaphene may be used to represent both Toxaphene and technical Chlordane.

2.2.2. Optionally, recalculate the DL using the formulas in 1.1.7. or 1.2.7.

2.3. Blank Check: For all methods, check the blank results against the DL. If 5% or more blank results (after outlier removal) are greater than the DL, raise the DL as follows:

- ***to the highest result if less than 20 method blanks are available.***
- ***to the next to the highest result if 20-100 method blanks are available.***
- ***to the level exceeded by 1% of the method blanks if there are more than 100.***

Only a blank that meets method specified qualitative identification criteria (where applicable) should be given a numerical result.

2.3. Qualitative Identification Check: At least 95% of the QL spiked data for each analyte must meet the qualitative identification criteria in the method. If 5% or more do not meet the qualitative criteria, then raise the QL and the spiking level to a level at which the qualitative identification criteria can be reliably met.

2.5. Lowest Expected Result (LER) Check: Estimate the lowest expected result (LER) from spikes at the QL. See Section 1.2.9.

2.5.1. Compare the LER to the DL. If the LER is less than the DL then the QL is raised according to the equation in Section 1.2.10.

2.5.2. Do NOT adjust the spiking level for ongoing QL verification (see Section 2) unless the spiking level is outside the range of half to twice the new QL. It is also necessary to adjust the spiking level if the spike results are not meeting the qualitative identification criteria in the method.

2.6. Precision and Accuracy Check: Determine the mean recovery and relative standard deviation of the QL spike results. If precision and accuracy requirements are not met, then the QL and spiking level must be raised

2.7. If the QL can be lowered by a factor of two or more, without causing the LER to be below the DL, qualitative identification can still be reliably maintained, and precision and accuracy requirements are met, then the QL, optionally, may be lowered. If the spiking level is then outside the range of half to twice the new QL, then the spiking concentration must be adjusted accordingly.

2.8. After verification, if the assessment process indicates that the DL or QL have increased by a factor of two or more, labs should investigate causes and take appropriate corrective action when necessary.

3. REPORTING DATA

3.1. The QL as described above is the lowest level for reporting quantitative results, but data may be reported down to the DL. If the requirements for quantitation cannot be met at any level, report all data as estimated.

For example, if the QL is 2.0 and DL is 0.6 then results are reported as follows:

Instrument result Reported Result

2.1 2.1

1.9 1.9J or DNQ

0.91 0.9J or 0.91J or DNQ

0.54 <0.6 or 0.6U or ND

ND <0.6 or 0.6U or ND

"DNQ:" Detected, Not Quantified

"U": A flag indicating non-detect

"J": A flag indicating increased uncertainty in the results

4. MATRIX EFFECTS

4.1. Optionally, to demonstrate whether or not you can achieve your estimated DL and QL in a specific matrix:

1) analyze the unspiked matrix to demonstrate that the analyte is below the DL and,

2) analyze a QL spiked matrix to demonstrate that the QL criteria can be achieved.

This procedure as outlined below could be applied to various matrices providing an analyte free matrix could be obtained. The procedure outlined in 4.1 will not allow False Positives caused by a Matrix Effect to be distinguished from true positive results.

Final Report

APPENDIX A: Committee Charter

Table 1.

K values for n replicates

n	K	n	K
7	6.101	54	2.977
8	5.529	55	2.97
9	5.127	56	2.963
10	4.829	57	2.956
11	4.599	58	2.949
12	4.415	59	2.943
13	4.264	60	2.936
14	4.138	61	2.93
15	4.031	62	2.924
16	3.939	63	2.919
17	3.859	64	2.913
18	3.789	65	2.907
19	3.726	66	2.902
20	3.67	67	2.897

21	3.619		68	2.892	
22	3.573		69	2.887	
23	3.532		70	2.882	
24	3.494		71	2.877	
25	3.458		72	2.873	
26	3.426		73	2.868	
27	3.396		74	2.864	
28	3.368		75	2.86	
29	3.342		76	2.855	
30	3.317		77	2.851	
31	3.295		78	2.847	
32	3.273		79	2.843	
33	3.253		80	2.839	
34	3.234		81	2.836	
35	3.216		82	2.832	
36	3.199		83	2.828	
37	3.182		84	2.825	

38	3.167	85	2.821
39	3.152	86	2.818
40	3.138	87	2.815
41	3.125	88	2.811
42	3.112	89	2.808
43	3.100	90	2.805
44	3.088	91	2.802
45	3.066	92	2.799
46	3.055	93	2.796
47	3.045	94	2.793
48	3.036	95	2.79
49	3.027	96	2.787
50	3.018	97	2.784
51	3.009	98	2.782
52	3.001	99	
53	2.993	100	

APPENDIX A: Committee Charter

If n >100 use values for n=100.

Table 2.

99th and 95th percentile t values for n replicates

n	$t_{(1-\alpha)}$=0.99	$t_{(1-\alpha)}$=0.95	n	$t_{(1-\alpha)}$=0.99	$t_{(1-\alpha)}$=0.95
7	3.143	1.943	54	2.399	1.674
8	2.998	1.895	55	2.397	1.674
9	2.896	1.860	56	2.396	1.673
10	2.821	1.833	57	2.395	1.673
11	2.764	1.812	58	2.394	1.672
12	2.718	1.796	59	2.392	1.672
13	2.681	1.782	60	2.391	1.671
14	2.650	1.771	61	2.390	1.671
15	2.624	1.761	62	2.389	1.670
16	2.602	1.753	63	2.388	1.670
17	2.583	1.746	64	2.387	1.669
18	2.567	1.740	65	2.386	1.669
19	2.552	1.734	66	2.385	1.669

20	2.539	1.729	67	2.384	1.668
21	2.528	1.725	68	2.383	1.668
22	2.518	1.721	69	2.382	1.668
23	2.508	1.717	70	2.382	1.667
24	2.500	1.714	71	2.381	1.667
25	2.492	1.711	72	2.380	1.667
26	2.485	1.708	73	2.379	1.666
27	2.479	1.706	74	2.379	1.666
28	2.473	1.703	75	2.378	1.666
29	2.467	1.701	76	2.377	1.665
30	2.462	1.699	77	2.376	1.665
31	2.457	1.697	78	2.376	1.665
32	2.453	1.696	79	2.375	1.665
33	2.449	1.694	80	2.374	1.664
34	2.445	1.692	81	2.374	1.664
35	2.441	1.691	82	2.373	1.664
36	2.438	1.690	83	2.373	1.664

37	2.434	1.688	84	2.372	1.663
38	2.431	1.687	85	2.372	1.663
39	2.429	1.686	86	2.371	1.663
40	2.426	1.685	87	2.370	1.663
41	2.423	1.684	88	2.370	1.663
42	2.421	1.683	89	2.369	1.662
43	2.418	1.682	90	2.369	1.662
44	2.416	1.681	91	2.368	1.662
45	2.414	1.680	92	2.368	1.662
46	2.412	1.679	93	2.368	1.662
47	2.410	1.679	94	2.367	1.661
48	2.408	1.678	95	2.367	1.661
49	2.407	1.677	96	2.366	1.661
50	2.405	1.677	97	2.366	1.661
51	2.403	1.676	98	2.365	1.661
52	2.402	1.675	99	2.365	1.661
53	2.400	1.675	100	2.365	1.660

APPENDIX A: Committee Charter

If n >100 use values for n=100.

APPENDIX E:

FACDQ Recommendations on Uses of Detection and Quantitation in Clean Water Act Programs

This Draft Revised Uses document incorporates changes made by the Policy Work Group on August 20 and August 30, as well as Policy Work Group authorized assignment changes and was distributed at the September 19-21 Committee meeting.

7. **Lab-Determined Detection Limits and Quantitation Limits**

   Recommendation: The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure shall[3] be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

8. **Matrix Effects**

   Recommendation: The FACDQ recommends that EPA consider how matrix effects impact detection and quantitation. The FACDQ requests that the Policy Work Group bring back a conceptual recommendation including details to be considered.

9. **Verification of Laboratory Proficiency of Detection and Quantitation Limits**

   Recommendation: The FACDQ recommends developing a process for verification of detection and

1 The FACDQ recognizes that EPA cannot commit to promulgate the recommendations of the FACDQ without the benefit of public notice and comment. Wherever "promulgate" appears in the FACDQ recommendations, the FACDQ expects that EPA will propose a rule consistent with the FACDQ recommendations and then finalize a rule that fully considers those public comments.

2 This procedure was created via modifications to the ACIL.

3 The Policy Work Group proposes that a small subgroup of the Policy Work Group examine each "shall," "should," and "must" to determine if they are being appropriately used.

quantitation limits by laboratories which will strive for feasibility, practicality, representativeness, and cost-effectiveness. This recommendation includes the following guidance:

- The process should include separate initial and on-going verification of Laboratory Detection and Quantitation Limits.
- The process should verify that the method meets the chosen MQOs.
- The Laboratory Quantitation Limit must be equal to or lower than the National Quantitation Limit, if a National Quantitation Limit exists.

See Attachment A on pg. 8 for a minority opinion in favor of retaining the DL_{nat} in the Uses recommendations.

10.Promulgation of National Quantitation Limits Recommendation

See Attachment B on pg. 9 for background discussion on the following two alternatives:

Alternative 1

Initial Statement of Purpose

It is the intent of the FACDQ to recommend that EPA adopt National Quantitation Limits for method and analyte combinations, particularly where compliance with the CWA cannot be determined using currently approved analytical methods (e.g. if WQBELs are less than the analytical capability of the methods). National Quantitation Limits should be set at the lowest concentration possible using approved analytical methods. A National Quantitation Limit shall be published in each analytical method used to analyze an analyte that needs a National Quantitation Limit. National Quantitation Limits can be different for each method approved for a given analyte. National Quantitation Limits are costly to develop and are not needed for regulatory determination for most analytes currently regulated under the Clean Water Act.

New Method Promulgation

Recommendation A (Placeholder): The FACDQ recommends that EPA promulgate a [multi-laboratory or inter-laboratory] procedure recommended by the FACDQ for determining National Quantitation Limits.

Recommendation B: The FACDQ recommends that when the EPA promulgates future analytical methods in 40 CFR Part 136, National Quantitation Limits shall be created and included with the methods. A National Quantitation Limit shall be created for each analyte determined by a method using the procedure(s) in Recommendation A.

Currently, this recommendation would require method developers applying for ATP approval, and standard-setting organizations, to submit to EPA multi-laboratory quantitation limits consistent with the FACDQ's multi-laboratory recommendations. These multi-laboratory limits would serve as

National Quantitation Limits should the applicant's method later be promulgated in 40 CFR Part 136. For some standard-setting organizations, this may be a significant departure from what they do now. Moreover, some FACDQ members are concerned that this requirement may stifle the development of new methods. Many of the methods recently promulgated by EPA in Part 136 are the product of these outside organizations, reflecting advances in technologies that result in methods with greater sensitivity. Therefore, the FACDQ requests that EPA discuss and request public comment on this issue in the EPA Notice of Proposed Rulemaking that incorporates the recommendations of the FACDQ. Should significant concerns surface during public comment, EPA should make appropriate changes in the final rulemaking to ensure that the development of new methods is not adversely affected.

Future Updates of Promulgated Analytical Methods

Recommendation: The FACDQ recommends that EPA periodically review current capabilities of promulgated analytical methods and undertake updates based on priorities. Method updates shall include creation and incorporation of first-time or updated National Quantitation Limits. A National Quantitation Limit shall be created for each analyte determined by a method using the same procedure(s) as for new method promulgation. In determining update priorities, EPA should consider:

- Methods where there have been significant improvements in detection or quantitation limits
- Methods that do not contain National Quantitation Limits
- Cases where quantitation limits are critical to the permit program (e.g., those required for very low WQBELs)
- Analytes for which current methods provide poor performance or otherwise do not meet program needs
- Cost and resource considerations
- Information submitted by states and/or other qualified third parties.

EPA will work with method developers to update priority methods. EPA shall publish a Federal Register Notice announcing the methods it proposes to update to incorporate National Quantitation Limits. Provisions later in this document are for the purpose of providing EPA with robust data sets for updating and or creating National Quantitation Limits.

<u>Alternative 2</u>

Initial Statement of Purpose

APPENDIX A: Committee Charter

It is the intent of the FACDQ to recommend that EPA adopt National Quantitation Limits for analytes listed in 40 CFR 136 based on a list of priorities. National Quantitation Limits should be set at the lowest concentration possible using approved analytical methods when compliance with the CWA cannot be determined. However, for analytes when compliance with the CWA can be comfortably determined, EPA may set a QL-something else at a concentration that allows the maximum number of laboratories and approved methods to be used. National Quantitation Limits and QL something elses shall be published in a table in 40 CFR 136 by analyte. Labs may use any approved method for an analyte so long as the Laboratory Quantitation Limit is equal to or lower than the National Quantitation Limit or QL something else for the analyte. This will provide a level playing field for all laboratories and permittees and allows maximum analytical flexibility.

Creation and Update of National Quantitation Limits

Recommendation A (Placeholder)*:* The FACDQ recommends that EPA promulgate a [multi-laboratory or inter-laboratory] procedure recommended by the FACDQ for determining National Quantitation Limits.

Recommendation B: The FACDQ recommends that EPA periodically review capabilities of analytical methods for the purpose of establishing and updating National Quantitation Limits. Quantitation limits shall be evaluated by analyte and method using the procedure(s) in Recommendation A. For a given analyte, the method that EPA judges has the lowest quantitation limit shall be used as the basis for setting the National Quantitation Limit.

EPA shall prioritize its efforts to create National Quantitation Limits using these or other factors:

- Cases where method sensitivity issues are critical to Clean Water Act programs (e.g., analytes with very low WQBELs)
- Analytes for which available methods have seen significant improvements in detection or quantitation limits
- Analytes for which there are no current National Quantitation Limits
- Cost and resource considerations
- Information submitted by states and/or other qualified third parties

EPA will work with method developers and others to establish and update National Quantitation Limits. EPA shall publish a Federal Register Notice announcing the analytes for which it proposes to create or update National Quantitation Limits. Provisions later in this document are for the purpose of providing EPA with robust data sets for creating or updating National Quantitation Limits.

Alternative 3 Creation and Update of Method Quantitation Limits for Use in Setting National Quantitation Limits

New Method Promulgation

Recommendation A (Placeholder): The FACDQ recommends that EPA promulgate a [multi-laboratory or inter-laboratory] procedure recommended by the FACDQ for determining National Quantitation Limits.

Recommendation B: The FACDQ recommends that when the EPA promulgates future analytical methods in 40 CFR Part 136, Method Quantitation Limits shall be created and included with the methods. A Method Quantitation Limit shall be created for each analyte determined by a method using the procedure(s) in Recommendation A.

Currently, this recommendation would require method developers applying for ATP approval, and standard-setting organizations, to submit to EPA multi-laboratory quantitation limits consistent with the FACDQ's multi-laboratory recommendations. These multi-laboratory limits could serve as National Quantitation Limits should the applicant's method later be promulgated in 40 CFR Part 136. For some standard-setting organizations, this may be a significant departure from what they do now. Moreover, some FACDQ members are concerned that this requirement may stifle the development of new methods. Many of the methods recently promulgated by EPA in Part 136 are the product of these outside organizations, reflecting advances in technologies that result in methods with greater sensitivity. Therefore, the FACDQ requests that EPA discuss and request public comment on this issue in the EPA Notice of Proposed Rulemaking that incorporates the recommendations of the FACDQ. Should significant concerns surface during public comment, EPA should make appropriate changes in the final rulemaking to ensure that the development of new methods is not adversely affected.

Future Updates of Promulgated Analytical Methods

Recommendation: The FACDQ recommends that EPA periodically review current capabilities of promulgated analytical methods and work with method developers to update priority methods. Method updates shall include creation and incorporation of first-time or updated Method Quantitation Limits determined using the procedure in Recommendation A. EPA should prioritize its efforts to update analytical methods using these or other factors:

- Cases where method sensitivity issues are critical to Clean Water Act programs (e.g., analytes with very low WQBELs)
- Analytes for which available methods have seen significant improvements in detection or quantitation limits
- Analytes for which there are no current QLnats

- Cost and resource considerations
- Information submitted by states and/or other qualified third parties

EPA shall publish a Federal Register Notice announcing the methods it proposes to update to incorporate Method Quantitation Limits. Provisions later in this document are for the purpose of providing EPA with robust data sets for updating and or creating National Quantitation Limits.

Creation of National Quantitation Limits

Recommendation: The FACDQ recommends that EPA Periodically review methods to identify those suitable for use in setting National Quantitation Limits (QLnats) needed to implement the FACDQ recommended WQBEL permitting strategy. EPA shall promulgate a Table of QLnats by analyte. For a given analyte, the method that EPA judges has the lowest quantitation limit shall be used as the basis for setting the QLnat.

5. **Setting Permit Conditions, Reporting and Using Data, and Determining Compliance When the Water Quality Based Effluent Limit (WQBEL) is Less Than Detection and Quantitation Capabilities of Existing Methods**[1]

Recommendation: The FACDQ recommends that the following recommendations be incorporated into 40 CFR Part 122, as appropriate.

A. Recommendations for NPDES Permit and Compliance Uses When a National Quantitation Limit Exists

If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B.

7. **Permit Requirements Related to Detection and Quantitation**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 136:

1. The default quantitation limit to be included in the

1The language previously here, relating to WQBELs at concentrations less than quantitation limits, was recommended as more appropriate elsewhere within the Final Report text and has been removed from the Uses document.

permit (Permit Quantitation Limit) is the lowest Part 136 promulgated National Quantitation Limit unless the regulator determines that the Permit Quantitation Limit should be adjusted to account for sensitivity, selectivity, and/or matrix effects;

2. The permit shall contain a condition that the quantitation limit determined by the permittee's laboratory (Laboratory Quantitation Limit) shall be at or below the Permit Quantitation Limit. The permittee's laboratory may use any Part 136 method for which they can demonstrate a Laboratory Quantitation Limit at or below the Permit Quantitation Limit. If matrix effects have been given special attention in the permit then they would also have to be considered in compliance and enforcement.

3. The permit shall require the permittee to report the detection limit (Laboratory Detection Limit) and the Laboratory Quantitation Limit and maintain such information for a period of at least five years;

4. The permit shall require the permittee to maintain individual numeric results for a period of at least five years. The regulator may require the individual numeric result for any value that is greater than or equal to the Laboratory Detection Limit and less than the Permit Quantitation Limit be reported in a supplemental report.

5. The permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;

6. The Permit Quantitation Limit shall be applicable for the term of the permit unless the regulator reopens and modifies the permit; and

7. That EPA require the Laboratory Detection Limit, the Laboratory Quantitation Limit, and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS) for purposes of updating 40 CFR Part 136 National Quantitation Limits.

8. **Establishing Compliance Thresholds and Determining Compliance**

   Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 136:

   1. Regulators will set average and daily maximum permit limits at the WQBEL.

   2. Permittees must report to the regulator all information in the following manner on the Discharge Monitoring Report (DMR):

      i. To report daily maximum sample results:

      1. For values not detected at the Laboratory Detection Limit, report “not detected”.

      2. For values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit, report “detected less than the Permit Quantitation Limit”.

      3. For values greater than or equal to the Permit Quantitation Limit, report the actual numeric values.

      i. To report average sample results:

5. When all values used to calculate an average are not detected at the Laboratory Detection Limit, report “not detected”.

6. When all values used to calculate an average are “detected less than Permit Quantitation Limit,” report “detected less than the Permit Quantitation Limit.”

7. When values used to calculate an average are a combination of “not detected” and “detected less than the Permit Quantitation Limit”, report “detected less than the Permit Quantitation Limit”.

8. When any value used to calculate an average is greater than or equal to the Permit Quantitation Limit, report the calculated numeric average after assigning zero to any individual value reported either as “not detected” or “detected less than the Permit Quantitation Limit.”

   3. To determine NPDES permit compliance with results reported on the DMR, regulators will:

      i. Determine that any daily maximum or monthly average results reported as either “not detected” or “detected less than the Permit Quantitation Limit” are in compliance with the effluent limitation.

      ii. Compare any numeric results directly to the WQBEL

9. **Additional Permit Requirements**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 136: Permits shall include language that triggers additional steps when a "significant number" (to be determined in permitting process) of values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported on the DMR.

B. Recommendations for NPDES Permits and Compliance Uses When No National Quantitation Limit Exists, or if the Permitting Authority Requires Use of a Method More Sensitive than the Method for Which a National Quantitation Limit exists:

Recommendations:

1. In the absence of a National Quantitation Limit, the permitting authority is free to establish its method for determining compliance for analytes that have limits/water quality standards at a level lower than that which can be detected and/or quantified.

2. For a list of analytes as defined by EPA, the permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;

3. That EPA require the Laboratory Detection Limit and the Laboratory Quantitation Limit and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS) for purposes of updating 40 CFR Part 136 National Quantitation Limits.

6**. Great Lakes Initiative**

Recommendation: The FACDQ recommends that the FACDQ recommendations should not supersede the current Great Lakes Initiative provisions. The FACDQ believes that there is not a significant conflict between the FACDQ recommendations and the Great Lakes Initiative.

7**. Other Uses to Consider**

Recommendation: The FACDQ tabled the discussion on recommendations regarding the use of detection and quantitation for other uses including, but not limited to, the following:

- ambient monitoring 305(b)
- pretreatment

- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization
- reasonable potential analysis
- effluent guidelines development
- limit derivation
- development of water quality criteria

8**. Alternative Test Procedures**

Recommendation: The FACDQ tabled the option of developing specific recommendations to EPA on updating the Alternative Test Procedures (ATP) Program. The FACDQ, however, does recommend that the ATP Program be updated to be consistent with recommendations from this document.

Attachment A

Written by: **David Kimbrough**

Minority Report on DL-nat

At the December 2006 FACDQ meeting, the Committee voted unanimously on a document that recommended that EPA should establish National Quantitation Limits (QL-nats) and National Detection Limits (DL-nats) and publish them in a table in 40 CFR 136. The language about a table of QL-nats and DL-nats was withdrawn by the FACDQ at the June 2007 meeting. The PWG has also recommended that the entire concept of DL-nat be removed from all documents. At the July 25 meeting of the FACDQ the Committee was unable to reach consensus on withdrawing the DL-nat. There were two "not opposed" votes and one "opposed". This paper attempts to explain the minority position on this vote.

1. The first reason for keeping the concept of a DL-nat is to ensure that there is adequate "distance" between the DL-lab and the QL-nat. The FACDQ recommendations are for a two tiered approach with both a QL and DL. Results below the DL are reported as ND, results between the QL and DL are reported as DNQ, and results above the QL are reported as numeric values. ND and DNQ results are treated for averaging purposes as zero (i.e. not out of compliance) but there are important regulatory implications to DNQ results. Permittees reporting DNQs may be required to engage additional management practices such as increased or additional monitoring, special studies, or Pollutant Minimization Programs (PMPs). For this strategy to work, the values of QL and DL have be sufficiently different to allow for DNQs to be detected. In particular, it is by far most important when the WQBEL (or other regulatory limits) have lower concentrations than the capability of currently approved 40 CFR 136 analytical methodology can achieve. The FACDQ is proposing that at least in these cases, if not all, that a fixed QL-nat needs to be established. In having a DL-nat can be used as a ceiling on the DL-lab, ensuring that the DL-lab is not too high as to preclude the determination of DNQ.

2. The second reason for keeping the DL-nat is ensure equal protection to all receiving bodies with a given WQBEL and equity for all permittees discharging to receiving bodies with a given WQBEL. As noted above, the FACDQ recommended permitting strategy includes required management practices when DNQs are reported. As the pilot study showed, laboratories can produce DL-labs with concentrations that differ over orders of magnitude. If only the DL-lab is used, two permittees could be discharging water to a receiving body with the same concentration of an analyte, one would have to do a PMP and the other would not simply because of differences in the laboratory capability. In fact, with the range of differences in DLs seen in the pilot study, it would be possible for the dischargers with a higher concentration to have no PMP than a discharger with a lower concentration. This does not provide equal to protection to all waters nor equity to permittees.

Attachment B

Discussion of Alternatives for EPA Promulgation of QLnat

Work of the small group to investigate possibilities for QLnat promulgation (the small group was Tom Mugan, Richard Burrows, David Kimbrough and Michael Murray)

Alternative 1 in the August 15, 2007 Uses Document is basically the concept that was originally proposed perhaps a year or more ago.

The Alternative 1 proposal has two components.

- The first component would require a method developer of a new method to do the QL_{nat} procedure as part of method development and validation as part of the EPA promulgation procedure. The idea was that the QL_{nat} would be included with the method.

- The second component is a process that recommends that EPA update previously promulgated methods to include QL_{nats} (or update them) along with any other method improvements warranted. A number of Committee members have expressed the desire for EPA to undertake method updates on a much more regular basis. Again, the QL_{nat} would be included with the method.

The only significant recent change is that we had at one point added a process whereby a method developer could petition EPA for an exemption to the requirement to do the QL_{nat} procedure (multi-lab or inter-lab procedure). This was added in response to a concern that the requirement for new methods would stifle the development of new methods because method developers would have difficulty generating the QL_{nat}. *(This added language was later struck for several reasons including that it created a new administratively complex exemption process that could be problematic. As a possible solution, Mary Smith suggested that, when EPA proposes the requirement for QL_{nats} for new methods, it could specifically request comment on whether this requirement, if promulgated in the final rule, would stifle new method development.)*

The other change is the insertion of what is called an Initial Statement of Purpose as an additional explanation on the intent of the recommendation.

Alternative 2 was submitted in response to a continued concern that method developers would have

difficulty finding enough labs to generate the necessary data to run the QL_{nat} procedure due to the difficulty of finding enough labs to generate the necessary data to run the QL_{nat} procedure. Therefore, Alternative 2 only has the update component.

With only an update component, it seemed reasonable that, to save on costs, EPA would only undertake update for problem analytes and, for a given analyte, would invest effort only for the method it thought was the most sensitive. Therefore, Alternative 2 was drafted as an update by analyte, rather than an update by analyte and method.

Once that draft was on paper, David K. thought that we needed to have a QL_{nat} for every analyte (in a table). Alternative 2 was then modified to say that, for analytes where current methods exist that are capable to measuring to environmentally significant levels (non-bad boys), EPA may promulgate $QL_{somthing\ elses}$ (for lack of a better name) that were reflective of a value that represents the lowest environmentally significant level. The different name is to distinguish it from a QL_{nat} that is considered to be the lowest reasonably achievable level a lab can reach.

Again, the Statement of Purpose was added.

Alternative 3 is largely the same as alternative 1 except that it satisfies a desire by some members of the Policy Workgroup that QLnats be in a table by analyte. So, this alternative creates what I have called Method Quantitation Limits that could be the basis for promulgation, as a separate step (although it could happen simultaneously), of QLnats in part 122 (or part 123, I forget which we decided). Presumably all new methods would get a Method Quantitation Limit determined by the FACDQ multi-lab procedure but EPA would only translate these to QLnats as the need and priorities and dictate.

The Statement of Purpose was not added. Instead we tried to be clear as to the intent as we wrote the recommendations.

Analysis of Alternatives

The original vision of Alternative 1 came from the Hybrid Document many months ago. The idea was to set the ship in the right direction by developing QL_{nats} as we go forward. Thus, anytime a method is promulgated, either a new method or when an existing method is updated, a QL_{nat} would be generated and available for states to use for regulatory purposes.

The idea that implementation of the FACDQ's undertaking would need to be phased in carefully has guided a number of proposals in the uses document. If we develop a new method and do not generate a QL_{nat}, we may lose the opportunity that comes with the new method promulgation. History shows that bureaucratic momentum has a way of preventing EPA or states from re-opening a provision in law. Thus, while we may have good intentions of updating a method within a reasonably short time frame, the likelihood is not good.

A number of caucus groups have advocated for EPA being more responsive in promulgating and updating methods. Both alternatives recommend that EPA update methods to insert and revisit QL_{nats}. Would the hue and cry (and the pressure on EPA to update a method) be greater if an initially set QL_{nat} was demonstrated to be either too high or low or if there were no QL_{nat} at all?

We are trying to assess the validity of the concern of stifling method development. During a recent Policy WG discussion, Cary indicated that those applying for ATPs are already doing the QL_{nat} procedure. Cary is going to ask representatives of ASTM and Standard Methods if it might pose a problem with future methods they develop.[1]

One attractive aspect of providing QL_{nats} by analyte, as is the case in Alternative 2, is that this appears to avoid the perceived difficulty (discussed as part of the discussion on the Uses Document) of permit conditions in a situation where the only method that has a QL_{nat} is regarded to be not the most sensitive one. This difficulty has been identified on several occasions and fixes have been made to the Uses Document.

Having a single QL_{nat} for an analyte may cause difficulties when there may be one or more methods available and there are matrix effect issues for what would otherwise be the most sensitive method. Without each method having a QL_{nat}, there would be little basis for deciding which other method is most appropriate. If we go with this alternative, we may need to provide for solutions to those problems.

The Initial Statement of Purpose adds length. This might be needed in a regulation where the meaning of words could be used for legal argument. In this case, if we need additional words to clearly state our intent, I think they should appear in the recommendation itself.

1 ASTM and Standard Methods provided input on this issue during the August 28, 2007 FACDQ Teleconference Meeting.

APPENDIX F

Glossary of Terms

The intent of this glossary is to define terms, commonly used in association with detection and quantitation and in environmental laboratories, which may be unfamiliar to the lay person. The definitions are taken from various sources. Where available, citations are provided following the definition. A list of acronyms for the citations is included at the end of the document.

A-posteriori Detection – A binary detection decision based upon the observed (net) signal and a definite criterion of detection. It corresponds to the critical level, L_C. (Lloyd A. Currie, "Limits for Qualitative Detection and Quantitative Determination", Analytical Chemistry, 586-593, 1968)

A-priori Detection – An estimate, based on a knowledge of the probability distribution of a net signal, of the detection capabilities of a given measurement process. It corresponds to the detection limit, L_D. (Lloyd A. Currie, "Limits for Qualitative Detection and Quantitative Determination", Analytical Chemistry, 586-593, 1968)

Accuracy – The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components, which are due to sampling and analytical operations; a data quality indicator. (NELAC)

Alpha, () – The tolerated probability of a “false positive” (i.e. Type I error). See False Positive.

Analyst – The designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (NELAC)

APPENDIX A: Committee Charter

Analytical Response – A numerical observation whose magnitude is related to the amount or concentration of the analyte in a sample. One or more analytical responses (as specified by a method) are used, in conjunction with a calibration curve or factor), to produce an analytical result. (D.T.E. Hunt and A.L. Wilson. "The Chemical Analysis of Water")

Analytical Result - A numerical estimate of the concentration of an analyte in a sample, which is obtained by carrying out once the procedure specified in an analytical method. Note that a method may specify analysis of more than one portion of a sample in order to produce one analytical result. (D.T.E. Hunt and A.L. Wilson. "The Chemical Analysis of Water")

Audit – A systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity. (EPA-QAD)

Batch – Environmental samples that are prepared and/or analyzed together with the same process and personnel and using the same lot(s) of reagents. (NELAC)

Beta, () – The tolerated probability of a "false negative" (i.e. Type II error). See False Negative.

Bias – The constant or systematic distortion of a measurement process, different from random error, which manifests itself as a persistent positive or negative deviation from the known or true value. This can result from improper data collection, poorly calibrated analytical or sampling equipment, or limitations or errors in analytical methods and techniques. (EPA-QAD)

Blank – A specimen that is intended to contain none of the analytes of interest and which is subjected to the usual analytical or measurement process to establish a zero baseline or background value. (NELAC) Blanks include:

- Equipment Blank: a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)

- Field Blank: blank prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)

- Instrument Blank: a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

- Method Blank: a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. (NELAC)

- Reagent Blank: (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Blind Sample – A sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

Calibration – Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by material measure or a reference material, and the corresponding values realized by standards. (VIM)

Calibration Curve – The graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

Calibration Method – A defined technical procedure for performing a calibration. (NELAC)

Calibration Standard – A substance or reference material used to calibrate an instrument. (QAMS)

Censored Data – Date reported only as below or above some threshold. (USGS)

Censored Method – See Method.

Data Quality Objectives – Qualitative and quantitative statements derived from the DQO Planning Process that clarify the purpose of the study, define the most appropriate type of information to collect, determine the most appropriate conditions from which to collect that information, and specify tolerable levels of potential decision errors. (EPA-QAD)

Degrees of freedom – A statistical parameter, based on the amount of data (number of samples) used in a calculation.

Detection – To have obtained experimental evidence that the analyte concentration is greater than zero. (D.T.E. Hunt and A.L. Wilson. "The Chemical Analysis of Water," 2nd edition, 1986, page 289. The Royal Society of Chemistry, Burlington House, London W1V OBN)

Effluent Limitation (EL) – Restrictions established by a state or EPA on quantities, rates, and concentrations in pollutant discharges. (EPA-TRS)

Environmental Laboratory Advisory Board (ELAB) – A Federal Advisory Committee, with members appointed by EPA and composed of a balance of non-state, non-federal representatives, from the environmental laboratory community, and chaired by an ELAB member. (NELAC)

False Negative Quality Control Sample – The false negative quality control sample (FNQS) is a method blank (e.g., reagent water) or "clean" sample that is spiked at (or near) L_D with the analyte of interest and processed through the entire analytical procedure to verify that such a spike will produce a detection. (Osborn, Kenneth and Thomas Georgian. "The Limits of Method Detection Limits," *Water Environment & Technology* (December, 2004)).

False Negative – Concluding that the analyte is absent when in fact it is present.

False Positive – Concluding that the analyte is present when in fact it is absent.

Holding Times (Maximum Allowable Holding Times) – The maximum times that samples may be held, after the sample is taken, prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)

Hypothesis Test – A statistical procedure for determining if a sample provides sufficient evidence to reject or accept one statement regarding the population of interest in favor of an alternative statement. (EPA-QAD)

Inter-laboratory Procedure Study – A study where a centralized study design coordinator sends identical[1] samples to multiple different laboratories for analysis. The resulting raw data are analyzed by the study design coordinator by a given procedure to provide estimates of L_C, L_D and/or L_Q. The laboratories would generate only data that would be submitted to the study design coordinator who would compile the date, evaluate it and generate on inter-laboratory L_C, L_D and/or L_Q.

Inter-laboratory Test Comparison – Organization, performance and evaluation of tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions. (ASTM)

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample) – A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC)

Laboratory Duplicate – Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

L_C DETECTION – LAYPERSON'S DEFINITIONS -

1 Identical in every way possible including, but not limited to analyte concentrations, matrices, etc.

3. **Critical Value (L_C) -** The minimum result which can be reliably discriminated from a blank (for example, with a 99% confidence level).

4. **Critical Value (L_C)** – The lowest result that can be distinguished from the blank at a chosen level, α, of statistical confidence.

L_D DETECTION – LAYPERSON'S DEFINITIONS -

1. **Detection Limit (L_D) -** The lowest true concentration that will almost always be detected. (The Committee wants the term "detected" to be modified.)

2. **Detection Limit (L_D) -** The minimum detectable value is smallest amount or concentration of a particular substance in a sample that can be reliably detected by a specific measurement process.

3. **Detection Limit (L_D) -** The minimum true concentration that will return a result above the critical value given a specific measurement process and confidence level.

L_C DETECTION - STATISTICAL DEFINITIONS -

3. **Critical Value (L_C) -** Smallest measured amount or concentration of analyte in a sample that gives rise to a Type I error tolerance of alpha under the null hypothesis that the true amount or concentration of analyte in the sample is equal to that of a blank. (The alternative hypothesis is that the true amount or concentration of analyte is greater than that of a blank.)

4. **Critical Value (L_C) -** The minimum observed result such that the lower 100 (1-)% confidence limit on the result is greater than the mean of the method blanks.

L_D DETECTION - STATISTICAL DEFINITIONS -

1. **The Minimum Detectable Value (L_D) -** Once L_C is established, L_D is the smallest concentration or amount of analyte at which the tolerance for Type II error is equal to beta.

2. **The Minimum Detectable Value (Ld) -** The lowest true concentration such that the frequency that the result is greater than L_C will be 100% (1-).

L_Q QUANTITATION DEFINITIONS -

3. **Quantification Limit (L_Q)**: The smallest detectable concentration of analyte greater than the detection limit where the required** accuracy (precision & bias) is achieved for the intended purpose.

**Note: EPA requested additional conversation around the use of the word required in the definition.

Matrix – The material of which the sample is composed or the substrate containing the analyte of interest, such as waste water, stormwater, and biosolids. Also called medium or media. (EPA-QAD)

Matrix Effects – Manifestations of non-target analytes or physical/ chemical characteristics of a sample that prevents the quantification of the target analyte (i.e., the compound or element of interest being quantified by the test method) as it is routinely performed, typically adversely impacting the reliability of the determination. For example, a matrix effect can give rise to a high or low bias. (EPA-QAD)

Matrix Spike (spiked sample or fortified sample) – A sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS)

Maximum Contaminant Level (MCL) – This is a contaminant-specific standard for acceptable drinking water under SDWA. MCLs also may be used for purposes of RCRA (Resource Conservation and Recovery Act) ground water monitoring to reach contaminant-specific clean-up levels.

Measurement Quality Objectives – Qualitative and quantitative statements of the overall level of uncertainty that a decision maker is willing to accept in results or decisions derived from measurements. MQOs/DQOs provide the statistical framework for planning and managing measurement plans consistent with the data user's needs. (EPA-QAD)

Median – The middle number or center value of a set of data in which all the data are arranged in sequence. (www.asq.org/info/glossary/a.html)

Method – 1. See Test Method. 2. Logical sequence of operations, described generically, used in the performance of measurements. (EPA-QAD)

Censored Method – Analytical methods that frequently produce non-numerical results for blanks (i.e. ND for "non-detect"). (EPA-QAD)

Uncensored Method – Analytical methods that nearly always produce numerical values for method blanks. (EPA-QAD)

Method Blank – For aqueous analysis, an unspiked or non-fortified reagent water sample which proceeds through the entire testing method, including all preparatory and determinative steps. (EPA-QAD) NELAC states that this should be the same matrix as samples, already addressed under "Blank".

Multi-laboratory Procedure Study – A study where multiple laboratories individually perform a L_C, L_D and/or L_Q estimation procedure (usually using self-selected spiking concentrations) and those individual estimates are summarized in some fashion (e.g. averaging, upper or lower confidence intervals) to characterize some measure of how well the analytical method performs in qualified laboratories. The multi-lab procedure study would include two steps: First, each individual lab would conduct the analysis and generate their unique L_C, L_D and/or L_Q level. Second, those levels would then be compiled from all laboratories, evaluated, and based on criteria, used to propose multi-lab L_C, L_D and/or L_Q levels, where appropriate[1].

National Environmental Laboratory Accreditation Conference (NELAC) – A voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. (NELAC Appendix A, Glossary, July 2005)

National Environmental Laboratory Accreditation Program (NELAP) – The overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC Appendix A, Glossary, July 2005)

Numeric Target – A measurable value determined for the pollutant of concern which, if achieved, is expected to result in the attainment of water quality standards in the listed waterbody. (EPA-TRS)

1 If, for example, there was a determination that variations in instrument design or analytical technique resulted in sensitivity differences that could not realistically be pooled, they may be excluded based on criteria.

Outlier – An observation that is shown to have a low probability of belonging to a specified data population; any item rejected by the sampler, analyst, or data reviewer, usually accompanied by an attendant explanation.

Performance Based Measurement System (PBMS) – A set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner. (October 6, 1997 62 FR 52098)

Power – the probability of reporting an analyte as detected at a given true concentration when the analyte is actually present. Statistical power equals one minus the Type II error. The power is dependent on the true concentration of a sample. (Note: if L_C is defined in terms of the blank rather than a concentration of zero, this definition is inappropriate. The definition would be the probability of reporting the level of analyte in a sample is greater than that observed in a blank, given that the true concentration in the sample is greater than that of the blank.)

Practical Quantitation Level (PQL) – Means the lowest concentration that can be reliably measured within specified limits of precision and accuracy for a specific laboratory analytical method during routine laboratory operating conditions. (EPA-TRS)

Precision – The consistency of measurement values quantified by measures of dispersion such as the sample standard deviation. Precision must be defined in context – e.g., for a certain analyte, matrix, method, perhaps concentration, lab or group of labs. (NELAC)

Protocol – A detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis), which must be strictly followed. (EPA-QAD)

Quality Assurance – An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance [Project] Plan (QAPP) – A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

APPENDIX A: Committee Charter

Quality Control – The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

Quality Control Sample – An uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (EPA-QAD)

Quantification Limit – A performance characteristic that marks the ability of a Chemical Measurement Process to adequately "quantify" an analyte. (IUPAC)

Quantitation versus Quantification – These are considered equivalent and can be used interchangeably. Both are commonly used in the literature.

Range – The difference between the minimum and the maximum of a set of values. (EPA-QAD)

Recovery – The degree to which a methodology measures all of the analyte contained in a sample, often expressed in percent recovered.

Relative Standard Deviation (RSD) – The standard deviation expressed as a percentage of the mean (i.e., the coefficient of variation). Mathematically, it is the mean divided by the standard deviation times one hundred percent.

Replicate Analyses – The measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (NELAC)

Reporting Limit – The minimum value below which data are documented as non-detects. (EPA-QAD)

APPENDIX A: Committee Charter

Sample – A representative part or a single item from a larger whole or group especially when presented for inspection or shown as evidence of quality. (Webster's)

Sensitivity – Sensitivity generally refers to the capability of a method or instrument to discriminate between small differences in analyte concentration.

Spike – A known quantity of an analyte added to a sample for the purpose of determining recovery or efficiency (analyst spikes), or for quality control (blind spikes).

Standard Deviation – A computed measure of variability indicating the spread of the data set around the mean.

Standard Operating Procedures (SOPs) – A written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

Standard Uncertainty – Uncertainty of the result of a measurement expressed as a standard deviation. (NIST)

Test Method – An adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or published by a recognized authority. (NELAC)

Type I Error – See Alpha and False Positive.

Type II Error – See Beta and False Negative.

Uncensored Method – See Method.

Uncertainty – The range of values that contains the true value of what is being evaluated at some level of

confidence.

Uncertainty (of measurement) – A parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. (NIST)

Variability During Routine Operations – Changes during the routine running of samples that might contribute to variability of results. This might include instrument drift through the course of the day due to changes in the ion source (such as contamination from running samples), differences in performance of instruments used for the same analysis, difference in technique for different analysts, etc.

Water Quality Based Effluent Limit (WQBEL) – Effluent limitations applied to dischargers when mere technology-based limitations would cause violations of water quality standards. Usually WQBELs are applied to discharges into small streams. (EPA-TRS)

List of Acronyms

ASTM - ASTM Dictionary of Engineering Science and Technology, 9th Edition

EPA OSWER - US EPA Office of Surface Water

EPA-QAD - US EPA Quality Assurance Division

EPA-TRS – EPA Terminology Reference System

G&C - Gibbons and Coleman textbook

IUPAC – International Union of Pure and Applied Chemistry

NELAC - National Environmental Laboratory Accreditation Conference

NIST - National Institute of Standards and Testing

QAMS - US EPA Quality Assurance Management Section

USGS - US Geological Survey

VIM - International Vocabulary of Basic and General Terms in Meteorology

Webster's - Webster's Dictionary

APPENDIX G:

Contractor Information

Triangle Associates, Inc.

Triangle Associates is a consulting firm of professionals committed to helping people understand and resolve public policy issues and environmental conflicts. Triangle provides public involvement, facilitation/mediation services and environmental education programs to public agencies, businesses, and communities.

Triangle designs processes and programs that are tailored to the unique needs of each client.

- We serve as a neutral third party, helping clients resolve politically charged and scientifically complex issues.
- We facilitate the work of multi-party, collaborative groups to reach agreements that meet the needs of all parties. Our many successes include decisions about the future of old growth forests on the Olympic Peninsula, watershed management plans, reducing airport noise, clean up of Hanford's hazardous and radioactive waste, revitalization of an urban center, and keeping transportation projects on-track.
- We specialize in designing and carrying out comprehensive public involvement programs for public agencies so that communities are informed and can shape successful outcomes.
- We design and present innovative and award-winning educational programs for clients who want to reach out to students of all ages and provide them with the knowledge and tools to make smart choices in the future.

APPENDIX A: Committee Charter

Triangle's facilitation team for the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act programs included Alice Shorett, Robert Wheeler, Vicki King, Cole Gainer and Derek Van Marter.

A woman-owned business, Triangle was founded by Alice Shorett in 1979 and is now an employee-owned company. Additional information about the firm is available at www.triangleassociates.com.

CSC

CSC is a global leader in the information technology arena with 87,000 employees and 48 years of delivering high quality business results to Federal and commercial clients worldwide. We support a broad range of industries, including Government; Chemical, Energy and Natural Resources; Health Services; Transportation; Banking and Financial Services; Aerospace and Defense; Manufacturing; and Communications. CSC Environmental Solutions, has partnered with EPA for the last 29 years providing scientific, statistical, engineering, policy, regulatory, training, and information technology support that exceeds customer expectations. CSC Environmental Solutions currently supports water, hazardous waste, air, research and development, and pesticide programs, and EPA's Office of Environmental Information. Our primary focus is on ensuring that EPA has access to high quality data to support decision-making and that EPA's actions and the data that supports them are appropriately communicated to stakeholders. The majority of our work is in data assessment, analytical method development (chemistry, biochemistry, microbiological, molecular, and radiochemistry methods), statistical data applications, environmental study design and management, water security, laboratory program management, training/outreach, and information management for environmental programs.

CSC Staff who were involved supporting EPA's Office of Water during the FACDQ through the coordination and management of the FACDQ Pilot Study, evaluation of Pilot Study and other data, and supporting the FACDQ Technical Work Group with statistical and other analyses include Ken Miller, Kristin Leinberger, Harry McCarty, and Lynn Walters. Additional CSC staff who provided intense support in the processing and review of data during the FACDQ Pilot Study include Barbara Beard, Neal Jannelle, Julie Rest, Cristopher Robinson, Erin Salo, and Maria Vargas.

APPENDIX H

References & Web Links

REFERENCES

American National Standards Institute, U.S. Guide to the Expression of Uncertainty in Measurement, ANSI/NCSL Z540-2-1997 (R2002).

Currie, L.A., 1999, Nomenclature in Evaluation of Analytical Methods Including Detection and Quantification Capabilities[1] (IUPAC Recommendations 1995), *Analytica Chimica Acta*, 391:105-126.

Currie, L.A., 1999, Detection and Quantification Limits: Origins and Historical Overview, *Analytica Chimica Acta*, 391:127-134.

Currie, L.A., 2004, Detection and Quantification Limits: Basic Concepts, International Harmonization, and Outstanding ("Low-Level") Issues, *Applied Radiation and Isotopes*, 61:145-149.

US Code of Federal Regulations, Title 40, Part 132, Appendix F, Procedure 8.

US EPA, Water Quality Guidance for the Great Lakes System: Supplementary Information Document, EPA-820-B-95-001, March 1995, http://www.epa.gov/gli05u03/docs/usepa_sid.pdf.

US EPA, *Guidance on Environmental Data Verification and Data Validation (**QA/G-8**)*, EPA/240/R-02/004, November 2002, http://www.epa.gov/quality/qs-docs/g8-final.pdf.

US EPA, *Guidance on Systematic Planning Using the Data Quality Objectives Process (**QA/G-4**)*, EPA/240/B-06/001, February 2006, http://www.epa.gov/quality/qs-docs/g4-final.pdf.

WEB LINKS

http://www.epa.gov/waterscience/methods/

http://www.epa.gov/waterscience/methods/det/

http://www.epa.gov/waterscience/methods/det/faca/techworkgroup/

http://www.epa.gov/waterscience/methods/det/faca/policyworkgroup/